
TD_x[®] SYSTEM OPERATION MANUAL

List No. 9520-22

**CUSTOMER SUPPORT CENTER
800-527-1869 (USA)**

**For all other areas of the world,
please call your local
Customer Service Department.**

**ABBOTT LABORATORIES
Diagnostics Division
Abbott Park, IL 60064 U.S.A.**

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FOREWORD

Congratulations on becoming a proud operator of the TD_x System! Using state-of-the-art technology, we have designed your instrument so that it functions consistently and dependably on a day-to-day basis.

The TD_x System is backed by dedicated professionals who excel in engineering, training, and technical expertise. As a valued customer, we will teach you how to operate, maintain, and troubleshoot your instrument when you attend our PACE accredited* training program at our Dallas, Texas facility.

For continuing service, we also provide telephone technical assistance should your operator need additional information or assistance in diagnosing a problem. Twenty-four hour service is available by calling our toll-free number, 800-527-1869 (USA). For all other areas of the world, please call your local Customer Service Department.

If a problem should arise that cannot be resolved by telephone, on-site support is offered by Abbott's Field Engineers. These engineers are extensively trained in all disciplines of Abbott instrumentation which assures proficiency in diagnosing, isolating, and correcting problems.

Abbott Laboratories demonstrates dedication to productivity by manufacturing the highest quality, most reliable instrumentation available. We look forward to serving your needs in any way possible.

* Professional Acknowledgment for Continuing Education is a system designed by the American Society for Medical Technology to evaluate, approve and document continuing education activities.

PROPRIETARY INFORMATION

Abbott Laboratories' software programs are protected by copyright. All rights are reserved. This software was developed solely for use with Abbott Laboratories equipment and for *in vitro* diagnostic applications as specified in the operating instructions. All operating instructions must be followed. Copying or other reproduction of this program except for archival purposes is prohibited without the prior written consent of Abbott Laboratories, Diagnostics Division.

FOREWORD

March 1993

Dear Abbott TDx[®]/TDxFLx[®] Customer:

Abbott Laboratories recognizes the importance of complying with Approved Guidelines for Clinical Laboratory Procedure Manuals, especially National Committee for Clinical Laboratory Standards (NCCLS) Document GP2-A (1984) or GP2-A2 (1992).

The Abbott TDx[®]/TDxFLx[®] System Operation and Assays Manuals are in substantial compliance with the NCCLS Guidelines for developing laboratory procedure manuals. The College of American Pathologists (CAP) interprets substantial compliance as the following: "... the components of the Document are, where appropriate, included in the procedure manual. The format does not have to be identical to NCCLS GP2-A (1984) or GP2-A2 (1992)."

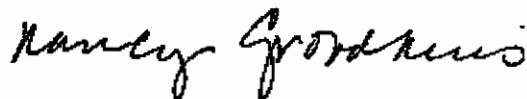
Both the CLIA 88 Final Rule (493.1211(c)), effective September 1, 1992 and the CAP Accreditation Inspection Checklist state that manufacturer's package inserts or operator manuals may be used, when applicable, to meet the requirements for a laboratory procedure manual. Any requirements not provided by the manufacturer must be provided by the laboratory. In addition, any variation from the printed package insert should be detailed in the laboratory procedure manual. Any modification to or deviation from the manufacturer's procedure manual, must be clearly documented.

Laboratory Procedure Manuals must be approved, signed and dated by the responsible person. The CAP requires a copy of NCCLS GP2-A or GP2-A2 to be available to the person responsible for the preparation of the procedure manual. This document can be ordered from NCCLS at (215) 525-2435.

The letter should be kept on file with your Abbott TDx[®]/TDxFLx[®] Operation/Assays Manual. If you have any further questions, please contact the Customer Support Center at 1-800-527-1869 (U.S.A.)

Thank you for your continued support of the Abbott TDx[®]/TDxFLx[®] System.

Sincerely,



Nancy Grondhuis
Manager, Laboratory
Quality Assurance

TDxFLx is a registered trademark of Abbott Laboratories.

ABBOTT INSTRUMENT WARRANTY

For U.S. Customers Only

Abbott Laboratories warrants the TD_x Instrument sold by the Abbott Diagnostic Division to be free from defects in workmanship and materials during normal use by the original purchaser, excluding items subject to normal wear and tear which require replacement with normal use. This warranty shall continue for a period of ninety (90) days commencing twenty-one (21) days from the date of Instrument shipment to the original purchaser, or until title is transferred from the original purchaser, whichever occurs first (the "Warranty Period").

If any defects occur during the Warranty Period, contact your Abbott Customer Support Center immediately, and be prepared to furnish pertinent details concerning the defect, the model number, and the serial number.

Warranty service is provided from 8:30 a.m. through 5:00 p.m., Monday through Friday, except on Abbott-observed holidays. Any service performed at other times, and all service required to correct defects or malfunctions not covered by this Warranty, will be billed at Abbott's labor rates then in effect.

This Warranty does not cover any defects or malfunctions which: (1) are not reported to Abbott during the Warranty Period and within one week of occurrence; (2) result from the use of any reagent, calibrator, sample cartridge, cuvette, centrifuge tube or other system disposable not supplied by Abbott Laboratories; (3) are caused by the reuse of sample cartridges, cuvettes or centrifuge tubes; (4) result from chemical decomposition or corrosion; (5) are caused primarily by failure to comply with any requirement or instruction contained in the current Abbott TD_x System Operation manual; or (6) result from maintenance, repair or modification performed without Abbott's authorization.

Abbott's liability for all matters arising from the supply, installation, use, repair and maintenance of the Instrument, whether arising under this Warranty or otherwise, shall be limited solely to the repair or (at Abbott's sole discretion) replacement of the instrument or of components thereof. In no event shall Abbott be liable for injuries sustained by third parties, incidental or consequential damages, or lost profits. Replaced parts shall become the property of Abbott Laboratories.

The foregoing is the sole warranty made by Abbott Laboratories regarding the instrument, and Abbott specifically disclaims all other warranties, expressed or implied, including the warranties of merchantability and of fitness for a Particular Purpose.

REVISION STATUS

The TD_x System is manufactured by Abbott Laboratories, Diagnostics Division, P. O. Box 152020, Irving, Texas, 75015-2020, U.S.A. Please direct all inquiries concerning information in this manual to the foregoing address.

The Revision Status of the manual is indicated below. Be sure that the manual contains the latest revision number of all pages. Additional copies of this manual may be purchased.

Note: Direct all inquiries regarding equipment problems to the Customer Support Center (CSC), Telephone No. 800-527-1869.

| Revision Number | Pages Revised and Added |
|--|---|
| Originally Issued – 9/85 | Not applicable. |
| Rev. 109 (Rev. 9.0 and 9.2 software) – 10/85 | pages iii, 3-19, 6-7, 6-8, 6-28a and b, 6-43, 6-47. |
| Rev. 110 (Rev. 9.2 software) – 11/85 | pages iii, 6-43. |
| Rev. 111 (Rev. 10.0 software) – 12/85 | pages iii, 1, 3-7, 10, 1-7, 1-25, 1-30, 1-31, 2-6-2-9, 3-4-3-6, 3-9-3-11, 3-14-3-38, 4-3-4-23, 4-35-4-37, 5-10, 5-29-5-32, 6-1.1-6-1.4, 6-12, 6-15, 6-19, 6-22, 6-28a and b, 6-30-6-83, Index, Assay Specific Curve Characteristics. |
| Rev. 112 (Rev. 10.0 software) – 4/86 | pages iii, 3-31, 6-46, 6-50, and Index page 1. |
| Rev. 113 (Revs. 9.0, 9.2 and 10.0 software) – 9/86 | Revs. 9.0 and 9.2 software – pages iii, 1-32, 3-19 and 5-25. Rev. 10.0 software – pages iii, 1-32, 3-21 and 5-25. |
| Rev. 114 (Rev. 11.0 software) – 1/87 | pages i-iii, 8, 9, 1-9, 1-14, 1-15, 1-21, 1-25, 1-30-1-33, 2-3, 2-7, 3-4-3-6, 3-9, 3-16-3-18, 3-21, 3-23, 3-26, 3-28-3-30, 3-32-3-37, 3-39, 4-2, 4-7, 4-8, 4-10, 4-12, 4-14, 4-19, 4-23, 4-24, 4-26, 4-34-4-36, 5-2, 5-4, 5-7, 5-9.1, 5-14, 5-15, 5-19-5-27, 5-30-5-32, 5-44, 6-1-6-1.4, 6-5, 6-7, 6-13, 6-17, 6-21, 6-22, 6-26, 6-27, 6-30, 6-31, 6-35-6-35.2, 6-41, 6-42, 6-45-6-53, 6-55, 6-55.1, 6-58, 6-59, 6-63.1, 6-65, 6-67, 6-71, 6-73, 6-74, 6-76-6-78, 6-81, 6-82 and Index pages 1-4. |
| Rev. 115 (Rev. 11.0 and 11.2 software) – 1/88 | pages iii, 6, 2-5, 2-8, 4-7, 4-8, 4-38, 5-36, 5-41, 5-43, 5-44, 6-1, 6-1.2, 6-2, 6-15, 6-32, 6-35.1, 6-41-6-44, 6-64, 6-66, 6-67, 6-77 and Index page 1. |
| Rev. 116 (Rev. 11.4 and 11.5 software) – 5/88 | pages i, ii, iii, 6, 7, 8, 10, 1-25, 2-3, 2-3.1, 2-4, 2-6, 3-20, 3-27, 4-3, 4-9, 5-4, 5-5, 5-9.1, 5-41, 5-43, 5-44, 6-1.1-6-1.4, 6-2, 6-4-6-6, 6-14, 6-25-6-29, 6-33, 6-34, 6-35, 6-42, 6-48-6-49.2, 6-50, 6-55, and 6-59. |
| Rev. 117 (Rev. 12.0 and 12.1 software) – 6/89 | All pages. |
| Rev. 118 (Rev. 12.0 and 12.1 software) – 8/89 | pages iii, 5-12, and 5-13. |
| Rev. 119 (Rev. 12.0 and 12.1 software) – 12/89 | pages iii, 1-9, 1-10, 1-15, 1-16, 1-25, 1-26, 3-21, 3-22, 3-41, 3-42, 5-22, 5-23, 6-3-6-6, 6-17-6-20a, 6-23, 6-24, 6-28a, 6-33, 6-34, 6-37-6-40, 6-45, 6-46, 6-55, 6-56, 6-69-6-72. |
| Rev. 120 (Rev. 15.0 software) – 7/92 | All pages. |
| Rev. 121 (Buffer reformulation) – 6/93 | vii, 1-3, 1-4. |

REVISION STATUS

| Revision Number | Pages Revised and Added |
|---------------------------------------|--|
| Rev. 122 (Rev. 15.1 software) – 12/93 | i, iii, iv, viii, 1, 2, 1-1, 1-4, 1-6, 1-7, 1-9-1-24, 1-27, 1-29-1-44, 2-1, 2-7, 2-8, 3-1, 3-2, 3-8, 3-10-3-14, 3-19-3-22, 3-24-3-28, 3-30, 3-31, 3-33, 3-35, 3-37-3-39, 3-42, 3-47, 4-2, 4-4-4-6, 4-8, 4-10, 4-11, 4-13, 4-16, 4-20, 4-23, 4-25, 4-37-4-39, 5-1, 5-3-5-7, 5-9, 5-10, 5-14-5-58, 6-1, 6-3-6-5, 6-8-6-11, 6-17, 6-22, 6-24, 6-34, 6-36, 6-37, 6-43, 6-44, 6-50, 6-55-6-57, 6-60, 6-61, 6-65-6-67, 6-70, 6-73-6-76, 6-79, 6-81, 6-84, 6-85, 6-90-6-94, 6-98, 6-100, I-1-I-6, A-1, A-3. |
| Rev. 123 – 09/94 | viii, 1-3, 1-29, 2-2, 2-7, 3-2, 4-12, 6-4, 6-41, 6-81, I-5. |

* User should record revision number and sign and date this log to provide a permanent record of revisions.

31789-120 ix TD_x[®] System Operation

All information necessary to the operation of the TD_x System is made available in this manual.

Use or Function is described in Section I, System Description.

Installation Procedures and special requirements are described in Section II, Unpacking and Installation.

Principles of Operation are described in Section III, Operation.

Performance Characteristics and Specifications are described in Section I, System Description.

Operating Instructions are described in Section III, Operation, Section IV, Diagnostic Checks, and Section V, Maintenance.

Calibration Procedures are described in Section III, Operation.

Operational Precautions and Limitations are described in Section I, System Description.

Hazards are described in Section I, System Description.

Service and Maintenance Information is described in Section V, Maintenance and Section VI, Troubleshooting.

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Introduction

This section provides details on:

- System Components
- Keypad Functions
- Method of Operation
 - Initialization Checks
 - Assay Process Sequence (Batch and Unit Dose)
- Performance Characteristics
- Specifications
- Operational Precautions and Limitations
- Theory of Operation

TD_x System

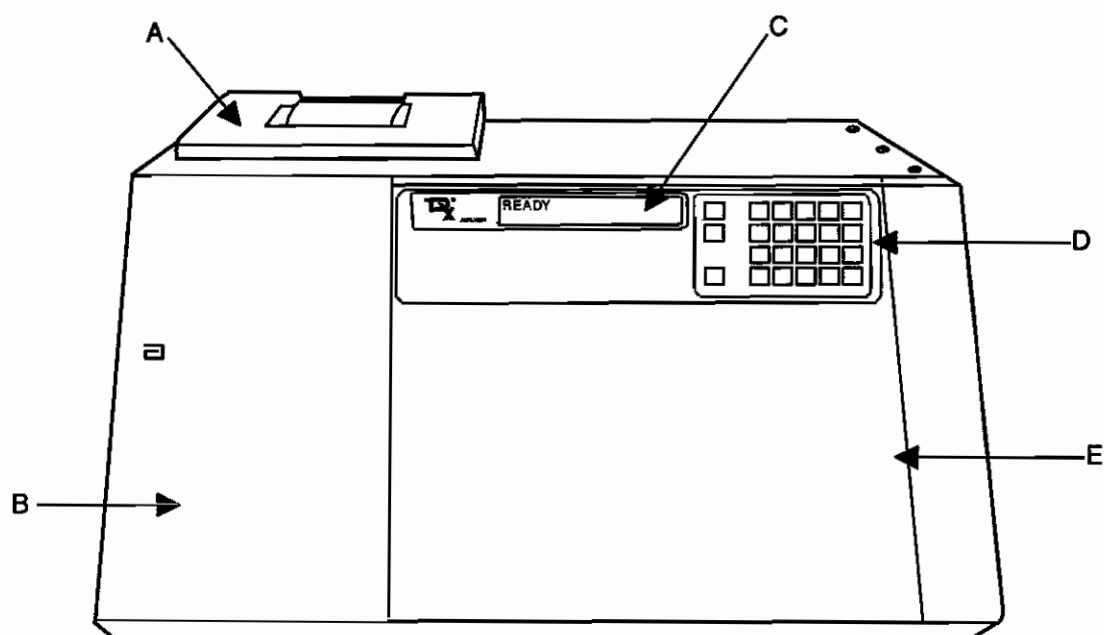
The TD_x System is an automated system which performs a variety of laboratory tests. Assays for therapeutic drugs, hormones, clinical chemistries, specific proteins and toxic/abused drugs can all be performed on this one automated instrument. The TD_x System is designed for use by a trained laboratory technician in hospitals and other laboratories.

This manual describes the TD_x System and its components, theory of operation, installation instructions, and operation procedures. In addition, the manual also provides the various diagnostic checks, maintenance procedures, and a troubleshooting guide.

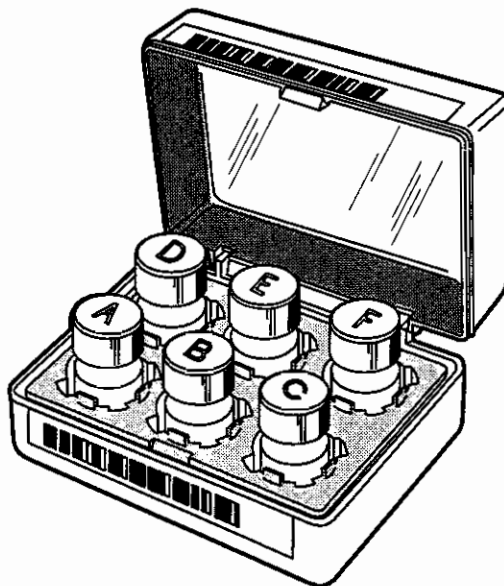
The TD_x System requires the following components (unless otherwise specified) for each assay.

The TD_x analyzer (No. 9520-XX). The external features shown are:

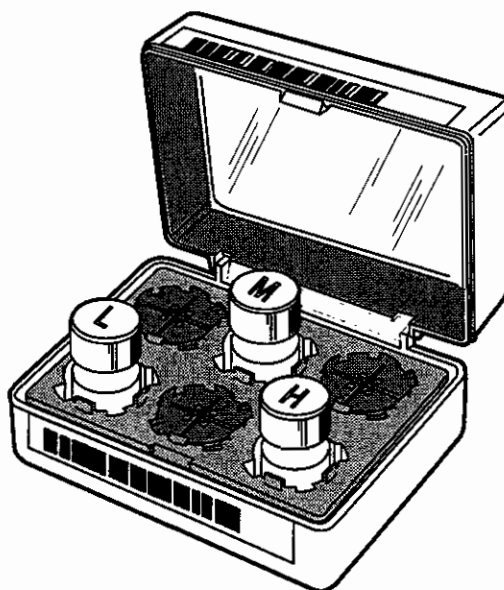
- A. printer
- B. buffer dispense cover
- C. display
- D. control key pad
- E. access door



X SYSTEMS[®] Calibrators. The calibrators consist of six vials, A through F. Refer to the appropriate assay section in the TD_x[®]/TD_xFL_x[®] Assays manual for more details.



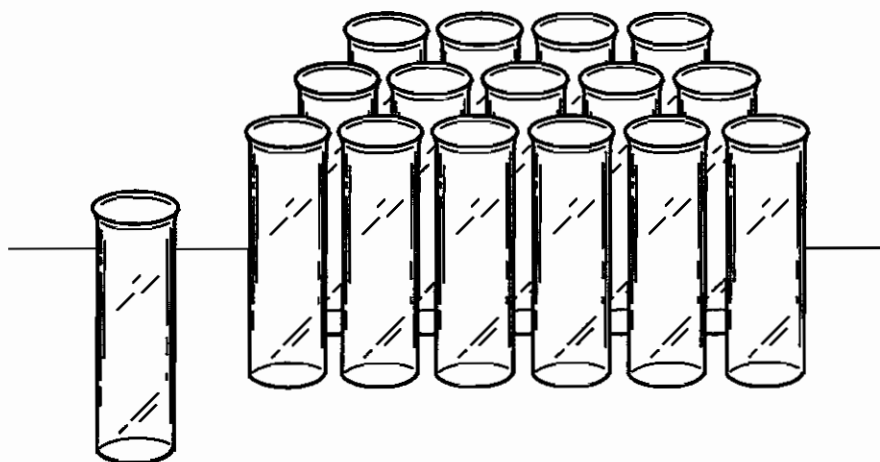
X SYSTEMS[®] Controls. The controls for most assays consist of three vials, Low, Medium, and High. Controls for some assays contain vial quantities other than three. For some assays there may be more than one type of control, for example, serum and urine controls. Refer to the appropriate assay section in the TD_x[®]/TD_xFL_x[®] Assays manual for more details.



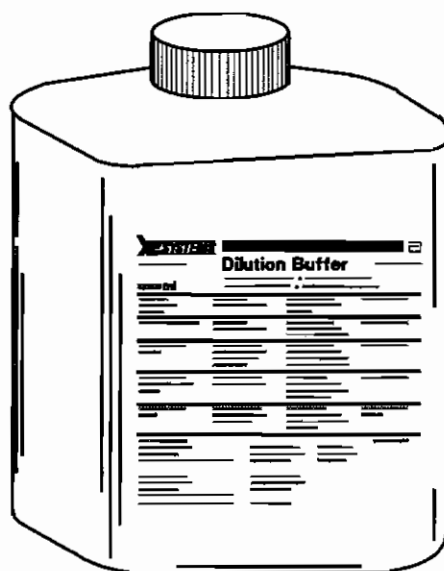
TD_xFL_x is a registered trademark of Abbott Laboratories.

X SYSTEMS is a registered trademark of Abbott Laboratories.

X SYSTEMS™ Cuvettes (No. 9518-06). Cuvettes are available in quantities of 100.



X SYSTEMS Dilution Buffer (No. 9519-02 or 9519-05). The dilution buffer is a 0.1M phosphate buffer containing 0.1% Sodium Azide as a preservative.

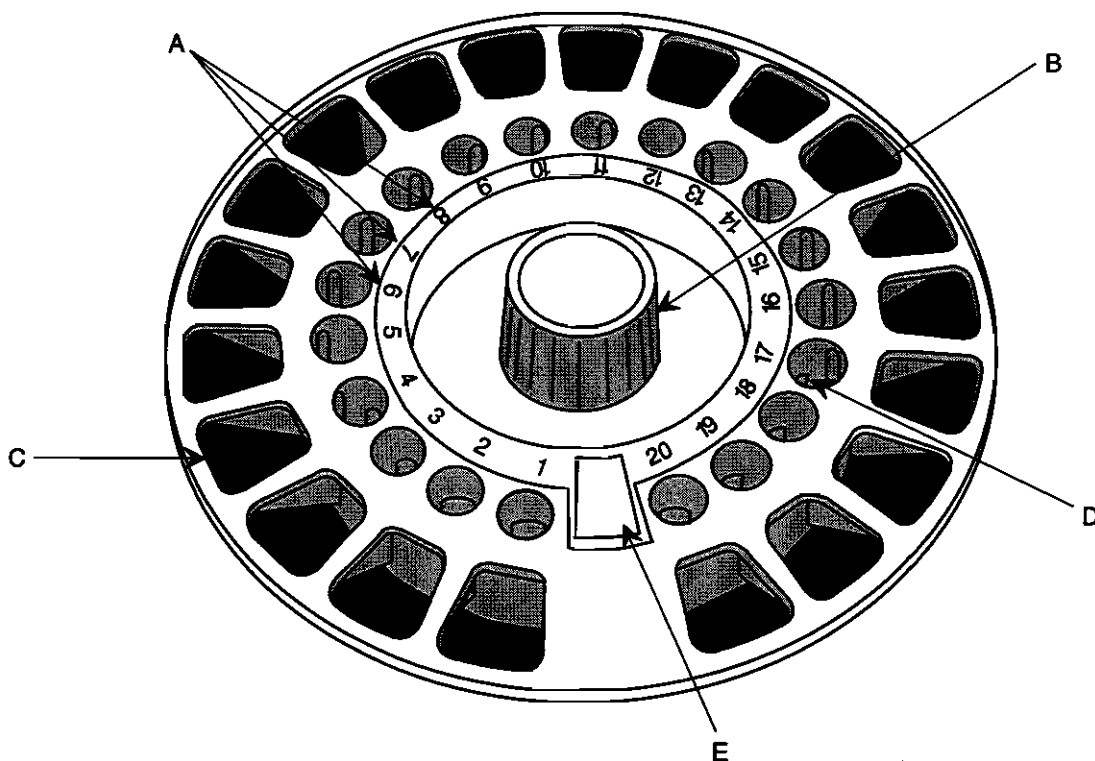


The TD_x System requires the following components for batch testing:

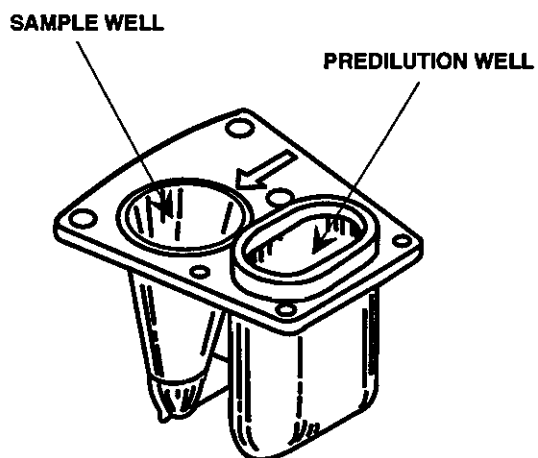
X SYSTEMS™ Carousel (No. 9518-11). The carousel is used for batch testing. The carousel contains:

- A. sample/cuvette position number
- B. carousel locking mechanism
- C. sample cartridge position
- D. cuvette position
- E. carousel barcode label position

Carousels are shipped with the instrument. Barcoded labels are included in the carousel box. The carousel accommodates up to 20 samples.



X SYSTEMS™ Sample Cartridges (No. 9518-05). These sample cartridges are used for batch testing and are available in quantities of 100. Sample cartridges have a sample well and a predilution well.



TD_x/TD_xFL_x[®] Reagent Packs are used to run in the batch mode. Refer to the assays manual for details on the contents of each vial.

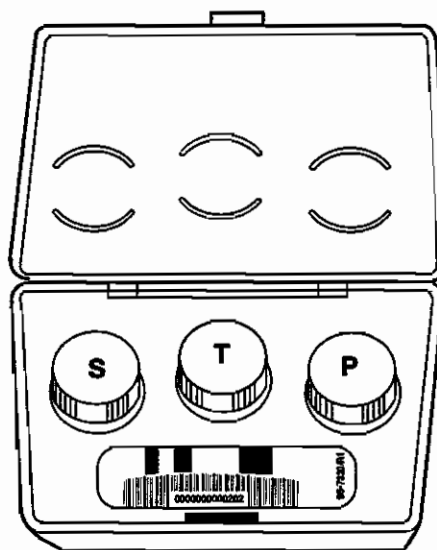
The 3-pot reagent pack consists of:

“S” - vial

"T" - vial

“P” - vial

NOTE: Vials in the T-Uptake reagent pack are in the order P - T - P.



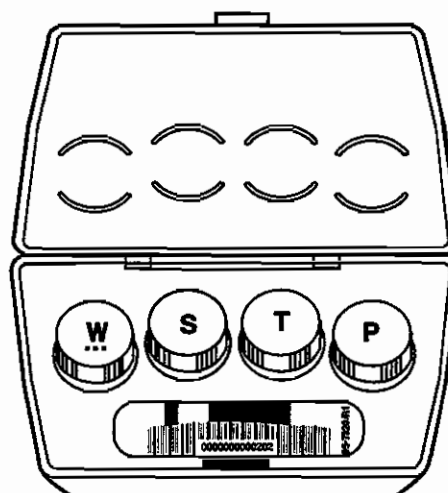
The 4-pot reagent pack consists of:

“W” - vial

"S" - vial

“T” - vial

“P” - vial

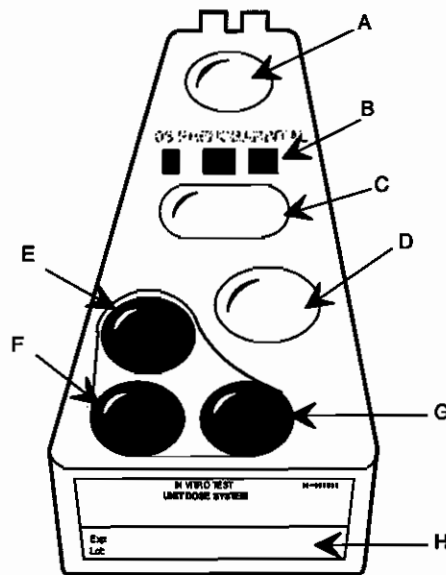


Unit Dose Reagent Cartridge.

The features of the unit dose cartridge are:

- A. cuvette well
- B. assay barcode label
- C. predilution well
- D. sample well
- E. "P" - well
- F. "S" - well
- G. "T" - well
- H. cartridge expiration date and lot number label


NOTE: Refer to the appropriate assay section of the assays manual for the contents of each reagent well.

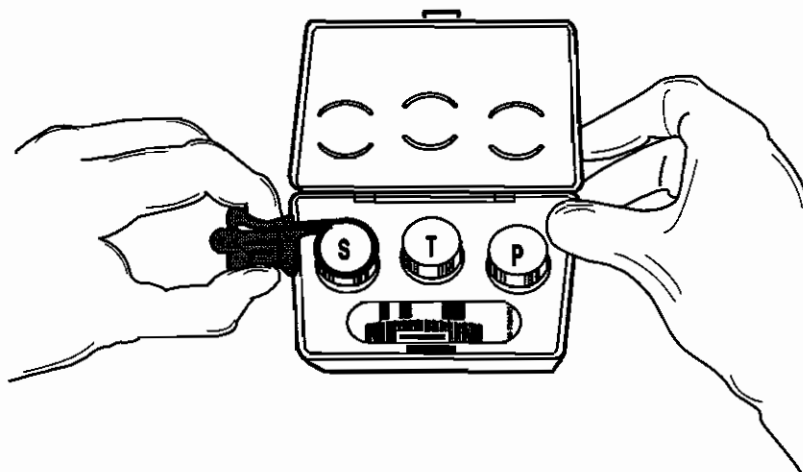


X SYSTEMS™ Wrench (No. 9684-25)


The X SYSTEMS™ wrench is provided to assist with loosening or tightening reagent vial lids.

To loosen a vial lid with the wrench, perform the following steps:

1. Hold the wrench so that the Abbott Laboratories logo () is face up.
2. Place the ring portion of the wrench around the vial lid.
3. Squeeze the opposite end of the wrench between your thumb and index finger.
4. Turn the wrench in a counterclockwise direction until the lid loosens.



To tighten a vial lid using the wrench, perform the following steps:

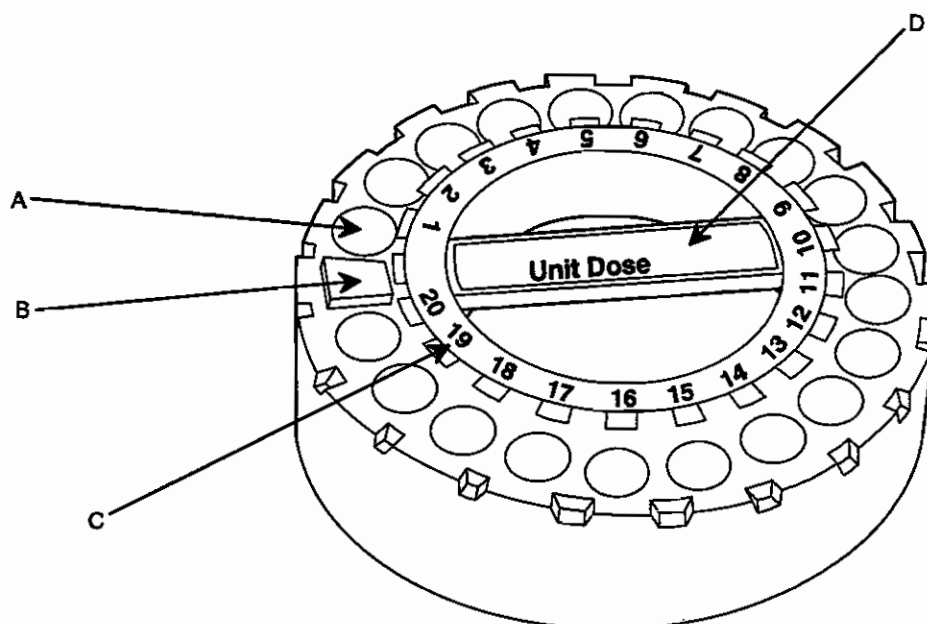
1. Hold the wrench so that the Abbott Laboratories logo () is face down.
2. Place the ring portion of the wrench around the vial lid.
3. Squeeze the opposite end of the wrench between your thumb and index finger.
4. Turn the wrench in a clockwise direction until the vial lid is tightened.

The Unit Dose Carousel (No. 9520-50) enables the TD_x System to perform unit dose testing.

The features of the unit dose carousel are:

- A. unit dose cartridge/cuvette position
- B. carousel barcode label position
- C. sample/cuvette position number
- D. carousel locking mechanism

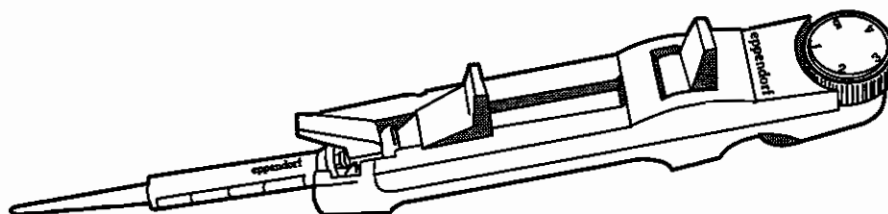
The carousel accommodates up to 20 individual unit dose reagent cartridges. Barcoded labels are included in the box with the unit dose carousels.



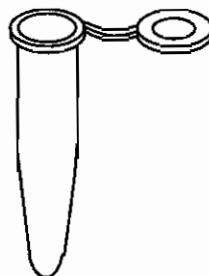
The TD_x System requires the following three products for assays requiring pretreatment steps:

NOTE: Any additional materials required for individual assays are described in the appropriate assays manual section.

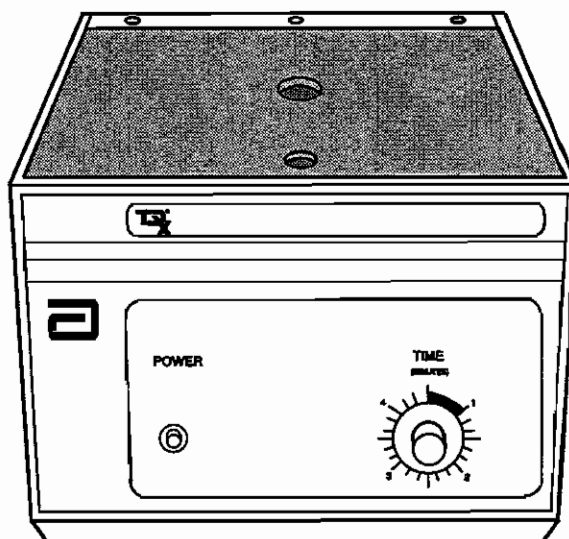
TD_x Precision Dispenser (No. 9528-02).



X SYSTEMS™ Centrifuge Tubes (No. 9527-40). Centrifuge tubes are available in quantities of 100.



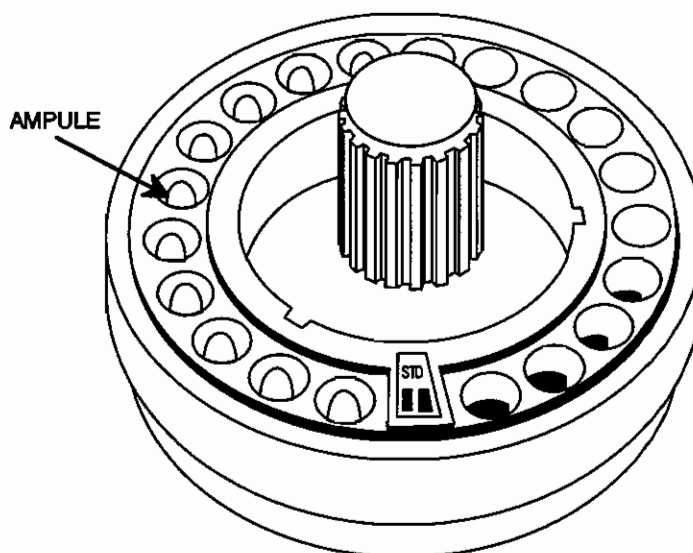
TD_x Centrifuge.
No. 9527-01, 100/110/120V, 50/60Hz.



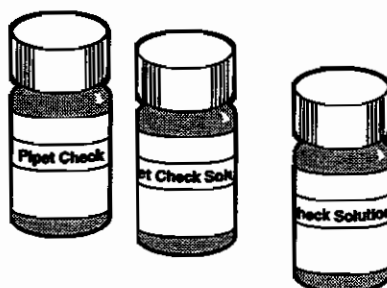
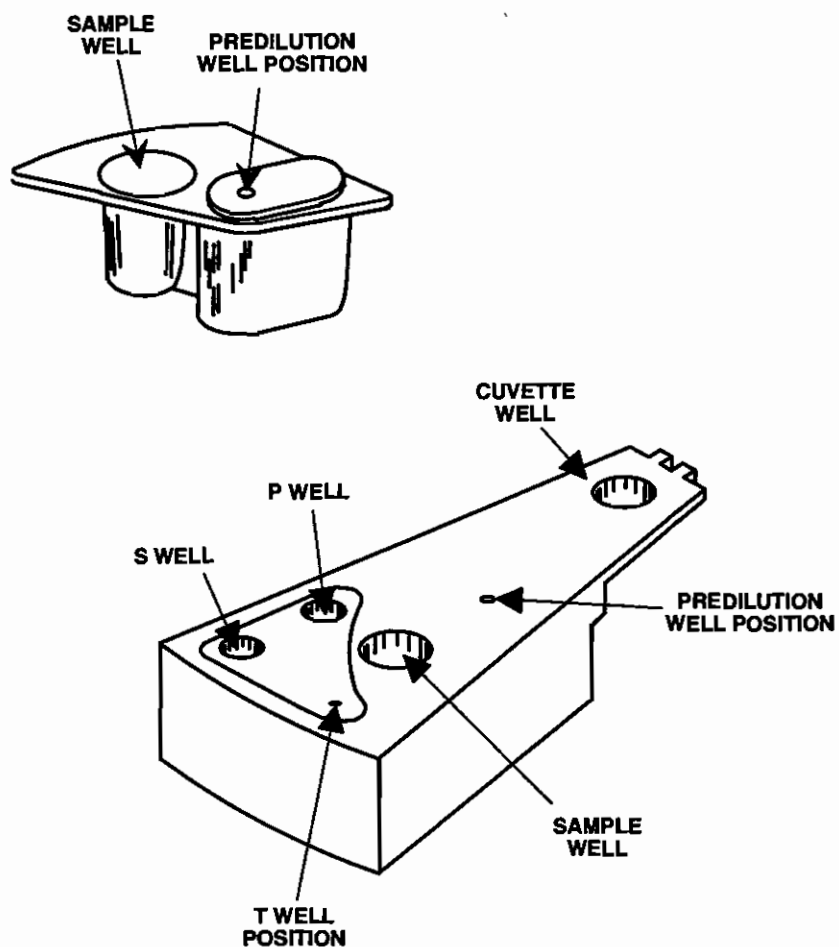
NOTE: For the X SYSTEMS™ Centrifuge, refer to the X SYSTEMS Centrifuge Instruction Guide.

The TD_x System requires the following three products for instrument specification checks and calibration procedures:

X SYSTEMS Fluorometric Standards Function Test Set Carousel (No. 9520-31) contains 10 sealed ampules of fluorescent dye (Rhodamine 110) in solution.



X SYSTEMS™ Pipet Check Solution (No. 9531-02)

Probe Positioning Cartridges
(No. 9520-28: Batch)
(No. 9520-41: Unit Dose)

The TD_x System uses the following manuals:

TD_x System Operation manual
List Number 9520-22

TD_x/TD_xFL_x[®] Assays manual
List Number 4A24-52

Both system manuals are shipped with the instrument.

The TD_x System

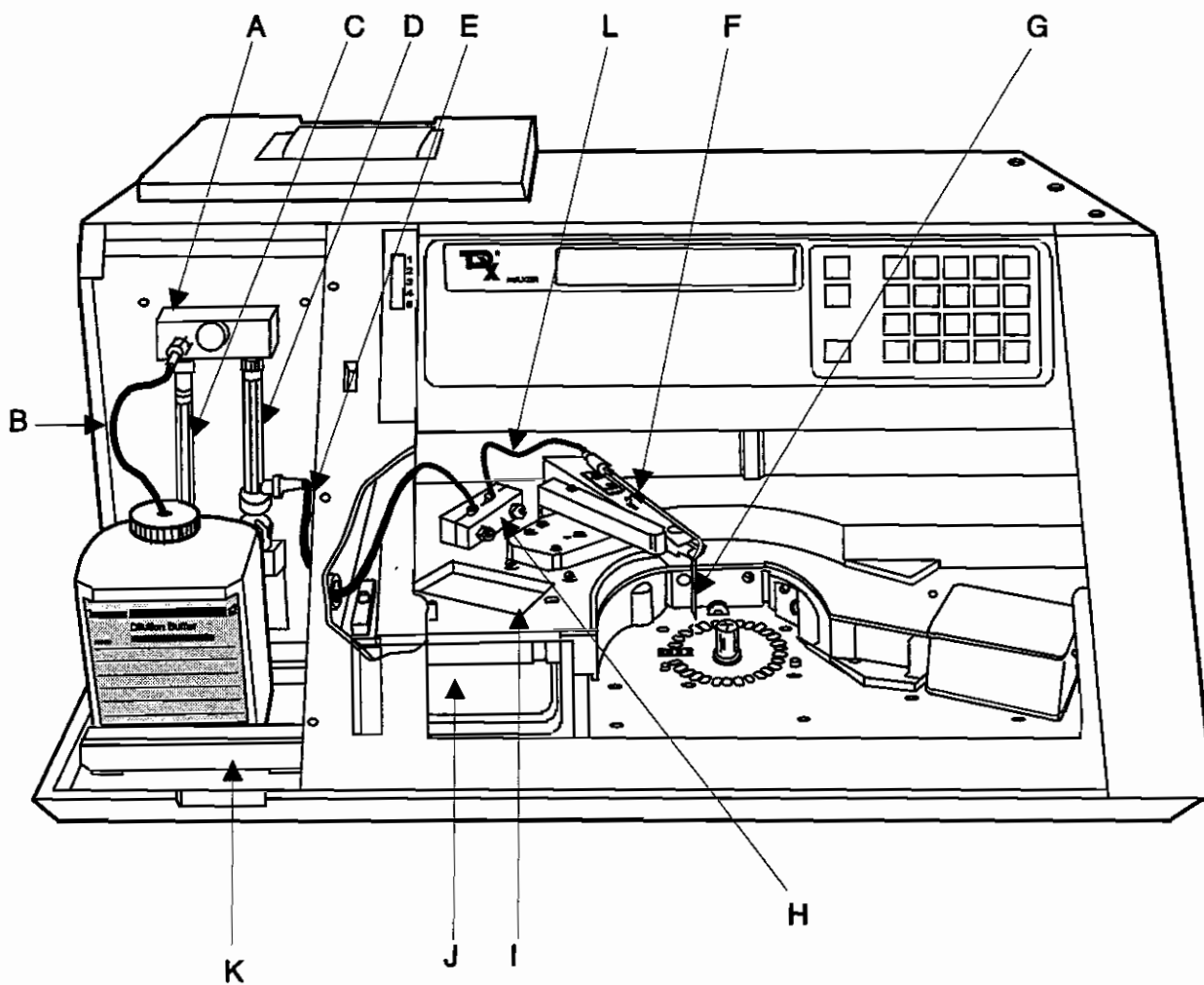
The internal components of the TD_x System consist of the:

1. dispenser assembly
2. optics assembly
3. sensors

Dispenser Assembly

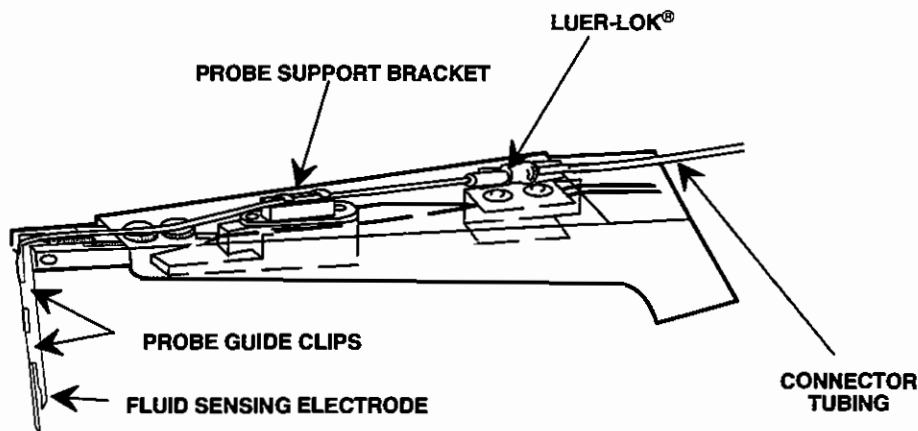
The features of the dispenser assembly are the:

- A. valve block
- B. inlet tubing
- C. diluent syringe
- D. sample syringe
- E. interconnect tubing
- F. boom arm
- G. probe
- H. liquid heater block
- I. reagent pack position
- J. waste container
- K. buffer platform
- L. probe connector tubing



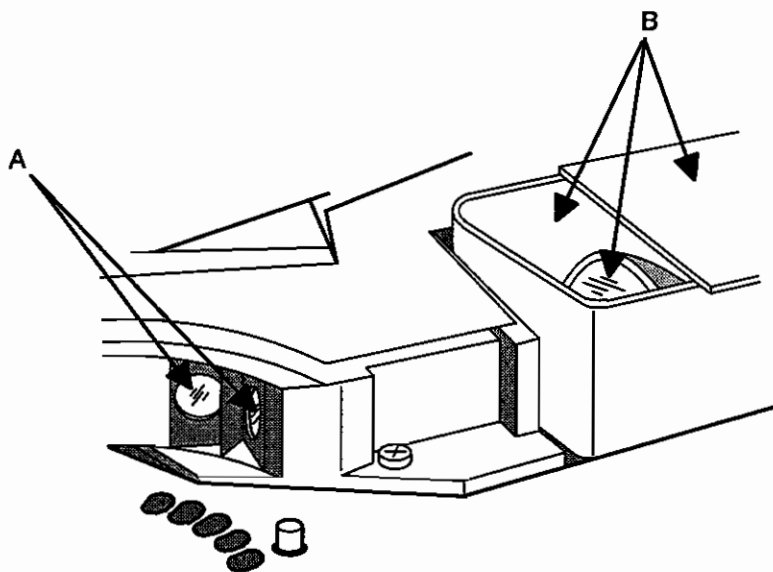
Probe

X SYSTEMS™ Stainless Steel Probe (No. 9967-02). The TEFLON® coated stainless steel probe features sturdy construction, fluid-sensing electrodes, and LUER-LOK® fitting for disconnect/reconnect.

**Optics Assembly**

The optics assembly features:

- A. two optical lenses
- B. a lamp, lamp housing, and lamp cover

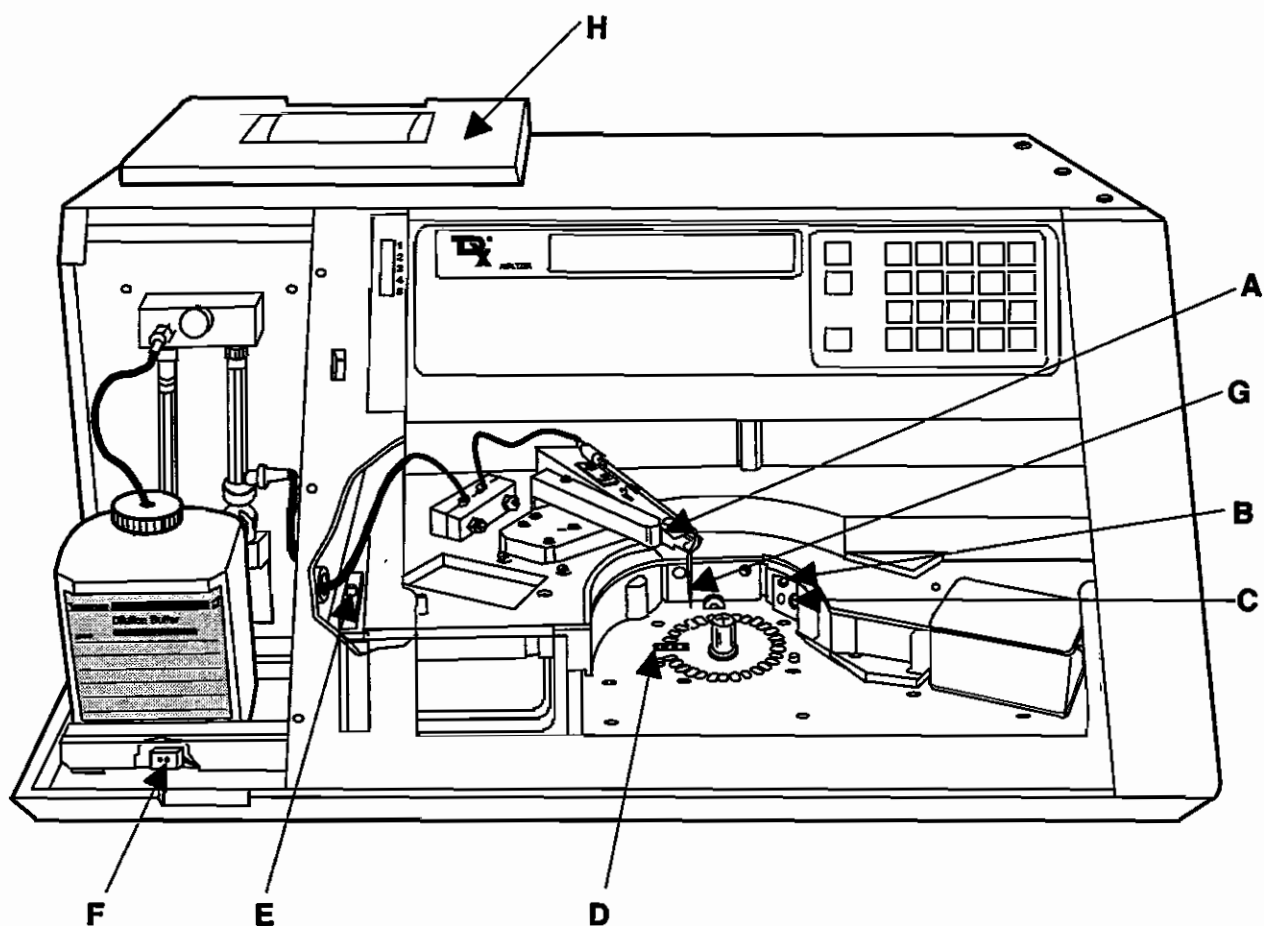


TEFLON is a registered trademark of E.I. duPont de Nemours & Co., Inc.
LUER-LOK is a Registered Trademark of Becton Dickinson & Co.

Sensors

The sensors in the TD_x System are the:

- A. barcode reader
- B. cuvette/locked-carousel sensor
- C. thermal detector
- D. carousel home sensor
- E. door sensor
- F. buffer sensor (underneath platform)
- G. liquid-level sensors
- H. paper out sensor (underneath cover)



The following is a description of the Keypad functions of the TD_x analyzer.

RUN Command

| | |
|---|---|
| RUN | Starts assay and calibration runs and some diagnostic checks. |
| ASSAY XX RUN (Batch Barcode Override) | Starts the particular batch assay indicated by the number XX, regardless of the reagent pack label or the carousel label. Barcode Override is described in Section III. |
| ASSAY “•” RUN (Unit Dose Barcode Override) | Starts a unit dose run, regardless of the carousel label. Unit dose barcode override is described in Section III. |
| TEST X.X RUN | Starts the instrument specification check, calibration procedure, or diagnostic test specified by the number X.X or X.X.X. |
| SYSTEM 4.1 RUN | Allows reprint of data from the last ASSAY or CAL run if data is available. |
| SYSTEM 4.2 RUN | Allows display of data from the last ASSAY or CAL run if data is available. |
| SYSTEM 5.1 RUN | Allows activation of new assays. |
| SYSTEM 5.2 RUN | Allows activation of new assays requiring more than one activation code. |

STOP Command

| | |
|------|---|
| STOP | Stops any assay, test, system, prime, or printout in progress. Returns the TD _x analyzer to READY. |
|------|---|

PRIME Command

PRIME Moves the boom arm to home, to the waste cup, and primes the dispenser assembly with buffer. **PRIME** only functions in the **READY** state. The carousel returns to home before the prime is initiated. You may press the **PRIME** key up to three times. The instrument then primes up to three consecutive times.

NOTE: Automatic primes are initiated if the liquid temperature is too high after a run.

PRINT or DISPLY Command

PRINT Advances the paper one line at a time.

ASSAY PRINT Prints the list of assays programmed in memory.

ASSAY XX PRINT Prints the parameters for the assay indicated by the assay number **XX**.

ASSAY XX.X PRINT Prints the assay parameter specified by the number **XX.X** along with remaining assay parameters.

SYSTEM PRINT Prints the system monitors programmed in memory.

SYSTEM X PRINT Prints the system status indicated by the number **X**.

SYSTEM X.X PRINT Prints the system parameter indicated by the number **X.X** along with the remaining system parameters.

TEST PRINT Prints the list of diagnostic test categories programmed in memory.

TEST X PRINT Lists subcategories of diagnostic tests within the major category indicated by the number **X**.

NOTE: If **DISPLY** is substituted for **PRINT** in any of the above commands, the data will be shown on the display instead of being printed. If the data consists of several lines, the succeeding line can be displayed by pressing the **NEXT** key.

**EDIT and STORE
Commands**

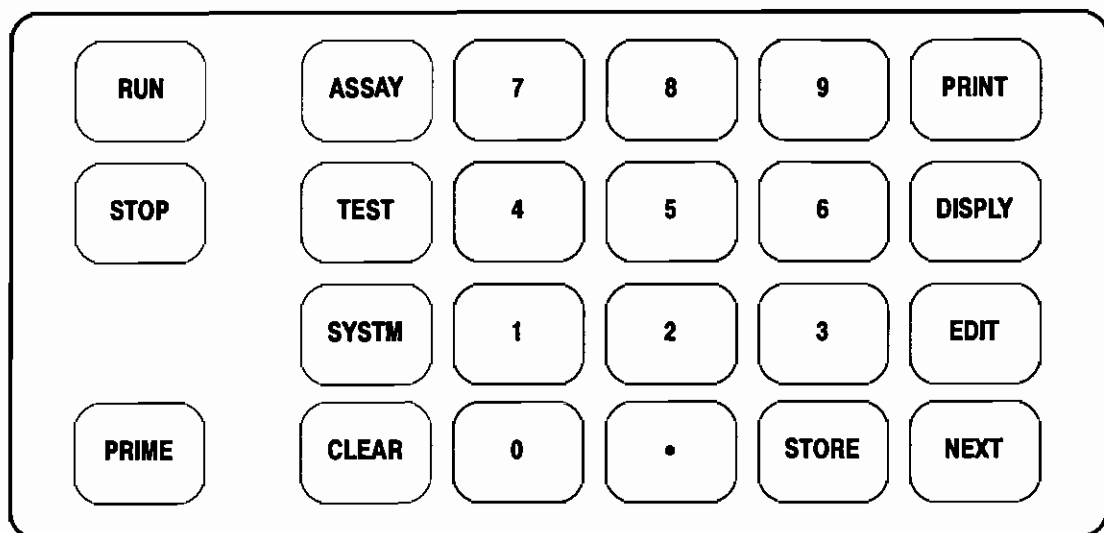
ASSAY XX.X EDIT
SYSTM X.X EDIT
TEST X.X.X EDIT

Displays the value requested by the parameter number XX.X, X.X, or X.X.X. New values are entered by pressing the appropriate numbers on the keypad and stored by pressing **STORE**. The numbers appear on the display as entered, but the new value is not substituted unless the **STORE** key is pressed.

If you wish to edit another parameter for this assay, system, or test, press **NEXT** until the parameter is displayed, enter the new value, and press **STORE**.

If an error is made when entering a number, press **CLEAR**, then enter the correct number.

NOTE: If the value is not intended for operator editing, the display will show [WRT PROTECT] and the value will not change.



Initialization Checks

The TD_x System operates in two modes: batch and unit dose. This section describes the initialization checks performed by the system prior to testing and the operating sequence for each mode.

Batch

Prior to testing in the batch mode of operation, the following sequence occurs after the **RUN** key is pressed:

1. The system checks that the door is closed (if System 2.2 is set to 1).
2. The system checks for a valid date.
3. The software checks the number of primes performed since the last [CHECK WASTE CUP] message was displayed.
4. The system checks that sufficient buffer is present.
5. The horizontal and vertical movement of the boom arm is checked as it seeks the R-boom and Z-boom home positions.
6. The system locates the carousel home position and verifies that the carousel is present and locked.
7. The system reads the carousel and reagent-pack labels and displays the assay name.
8. The lamp is turned on, and the intensity is checked.
9. Carousel Position 21 is rotated to the front of the optics to check for the presence of a Turbo[®] Carousel.
10. The system counts cuvettes by reflectance and checks for missing cuvettes.
11. The syringe and valve movement and home positions are checked.
12. The reagent liquid levels are checked to ensure that there is sufficient reagent in the reagent pack.
13. The system checks the ambient temperature.
14. The heater is activated until the cuvette surface temperature registers 35 degrees Celsius.

If the instrument fails to pass any one of these checks, an error message appears in the display, and the sequence stops. Refer to Section VI, Troubleshooting, for any error message.

Turbo is a registered trademark of Abbott Laboratories.

Unit Dose

Prior to testing in the unit dose mode of operation, the following sequence occurs after the **RUN** key is pressed:

1. The system checks that the door is closed (if System 2.2 is set to 1).
2. The system checks for a valid date.
3. The software checks the number of primes performed since the last [CHECK WASTE CUP] message was displayed.
4. The system checks that sufficient buffer is present.
5. The horizontal and vertical movement of the boom arm is checked as it seeks the R-boom and Z-boom home positions.
6. The system locates the carousel home position and verifies that the carousel is present and locked.
7. The system reads the carousel label.
8. The system counts cuvettes by reflectance and checks for missing cuvettes.
9. The system reads the unit dose cartridges and displays all assay names. The assay locations and calibration dates are printed.
10. The lamp is turned on, and the intensity is checked.
11. Carousel Position 21 is rotated to the front of the optics to check for the presence of a Turbo[®] Carousel.
12. The syringe and valve movement and home positions are checked.
13. The system checks the ambient temperature.
14. The heater is activated until the cuvette surface temperature registers 35 degrees Celsius.

If the instrument fails to pass any one of these checks, an error message appears in the display, and the sequence stops. Refer to Section VI, Troubleshooting, for any error message.

**Batch Assay
Process Sequence**

The process sequence for a batch assay occurs automatically after the TD_x analyzer door is closed, the **RUN** key is pressed, and the system has passed all initialization checks. The sequence follows:

Step 1 - The carousel moves sample/cuvette position number 1 to the dispense axis.

Step 2 - The first dispense cycle begins. The reagent is dispensed and sample is diluted in preparation for background readings. The display reads:

REV 1 PIPETTING

Step 3 - The carousel continues to rotate as Rev 1 pipetting continues until the first cuvette reaches the optical path. When required, background intensity readings are taken and stored for each cuvette. The display reads:

BLANK READING

Step 4 - The carousel rotates for blank readings until the first position returns to the dispense axis. The second dispense cycle begins. The display reads:

REV 2 PIPETTING

Step 5 - When the last sample position has been diluted and dispensed, the carousel revolves to maintain cuvette temperature for a time specific for the assay type. The display reads:

INCUBATING

Step 6 - Final intensity readings are taken on each cuvette. The display reads:

FINAL READING

Step 7 - Final intensity readings are corrected for background intensities. Polarization or percent intensity values, depending on assay technology, are calculated and converted to the appropriate concentration units.

Step 8 - The assay results are printed.

Step 9 - The paper supply is checked.

Step 10 - The display reads:

DONE-REMOVE RPAK

beeps, then displays

READY

If the carousel is not removed within 5 minutes following the completion of the run, the instrument beeps and displays:

REMOVE CAROUSEL

**Unit Dose Assay
Process Sequence**

The process sequence for a unit dose assay occurs automatically after the TD_x analyzer door is closed, the **RUN** key is pressed, and the system has passed all initialization checks. The sequence follows:

Step 1 - The unit dose carousel moves sample number 1 to the dispense axis.

Step 2 - The first dispense cycle begins. The reagent is dispensed and sample is diluted for background reading if required. The display reads:

REV 1 PIPETTING

Step 3 - As the unit dose carousel rotates during Rev 1 pipetting, and the first cuvette reaches the optical path, a background intensity reading, when required, is taken and stored. The display reads:

BLANK READING

Step 4 - After Rev 1 pipetting and as blank readings continue, the first sample position is returned to the dispense axis and the second dispense cycle begins. The display reads:

REV 2 PIPETTING

Step 5 - When sample number 1 reaches the optical path, and at the completion of Rev 2 pipetting for sample number 11, a final intensity reading is taken and the display reads:

FINAL READING

The display alternates between [REV 2 PIPETTING] and [FINAL READING] until Rev 2 pipetting is completed for all samples.

Step 6 - When Rev 2 pipetting is completed, the unit dose carousel rotates and the display reads:

INCUBATING

At the same time, a final intensity reading is taken on the remaining samples. The display reads:

FINAL READING

The display alternates between [INCUBATING] and [FINAL READING] until the remaining sample intensities are read.

Step 7 - Final intensity readings are corrected for background intensities. Polarization or percent intensity values, depending on assay technology, are calculated and converted to the appropriate concentration units.

Step 8 - The assay results are printed.

Step 9 - The paper supply is checked.

Step 10 - The display reads:

ASSAY COMPLETE

beeps once, then displays:

READY

If the carousel is not removed within 5 minutes following the completion of the run, the instrument beeps and displays:

REMOVE CAROUSEL

The following performance characteristics apply to the TD_x System and to its test components.

| Throughput | Batch Pipetting Sequence (minutes) | | | | | | |
|--|------------------------------------|---------|---------|-----------|---------|---------|---------|
| | Mode 1* | Mode 2 | Mode 3 | Mode 4 | Mode 5 | Mode 6 | Mode 7 |
| One sample: | 6 min. | 16 min. | 13 min. | 14 min. | 9 min. | 9 min. | 22 min. |
| Full carousel: | 13 min. | 24 min. | 20 min. | 25 min. | 19 min. | 18 min. | 30 min. |
| | Mode 8 | Mode 9 | Mode 10 | Mode 11 | Mode 12 | Mode 17 | Mode 19 |
| One sample: | 12 min. | 16 min. | 3 min. | 16 min. | 9 min. | 9 min. | 13 min. |
| Full carousel: | 18 min. | 26 min. | 28 min. | 25 min. | 20 min. | 15 min. | 20 min. |
| | Mode 21 | Mode 23 | Mode 25 | Mode 26 | Mode 27 | Mode 28 | Mode 30 |
| One sample: | 14 min. | 19 min. | 16 min. | 16 min. | 16 min. | 15 min. | 13 min. |
| Full carousel: | 19 min. | 30 min. | 24 min. | 24 min. | 22 min. | 23 min. | 19 min. |
| | Mode 31 | Mode 33 | Mode 37 | Mode 40 | Mode 42 | Mode 43 | |
| One sample: | 27 min. | 16 min. | 12 min. | 13 min. | 16 min. | 14 min. | |
| Full carousel: | 30 min. | 24 min. | 20 min. | 23 min. | 24 min. | 21 min. | |
| Unit Dose Pipetting Sequence (minutes) | | | | | | | |
| | Mode 1 | Mode 4 | Mode 17 | Mode 22** | Mode 23 | | |
| One Sample: | 9 min. | 16 min. | 9 min. | 24 min. | 26 min. | | |
| Full carousel: | 20 min. | 27 min. | 20 min. | 29 min. | 36 min. | | |

* Since most TD_x System assays are run in the Mode 1 pipetting sequence, it is described as follows. For more details on the sequences of pipetting modes, contact the Customer Support Center.

** Mode 22 is reserved for TD_x Turbo[®] (Specific Protein) assays.

Mode 1 Pipetting

After the instrument has passed all the initialization checks, the pipetting sequence begins. In Mode 1, sample is aspirated from the sample well and dispensed with X SYSTEMS™ Dilution Buffer into the predilution well of the sample cartridge. This dilution of sample provides greater accuracy of pipetting the sample volume, because a larger volume of diluted sample will be pipetted into the cuvette for the assay. One-half the final volume of the diluted sample, the “P” reagent and X SYSTEMS Dilution Buffer are dispensed into the cuvette to give one-half the final reaction volume. Background intensity readings are taken on this mixture. The second half of the diluted sample volume is added to the cuvette along with the “T” reagent, “S” reagent, and X SYSTEMS Dilution Buffer to give the final reaction volume. The cuvette is incubated until the reaction reaches equilibrium, then final intensity readings are taken.

SYSTEM DESCRIPTION**PERFORMANCE CHARACTERISTICS**

| | |
|---|--|
| Reagents, Calibrators, Controls, Unit Dose Cartridges, Pretreatment Reagents | Shipped ready-to-use Stable calibration TD _x [®] System products expire the last day of the month printed on the label, unless otherwise specified |
| Precision Dispenser | Spring-loaded plunger Repetitive pipettings Chemically inert disposable tip |
| TD_x[®] Analyzer | Automatically reads sample blank when required by the specific assay mode |
| TD_x[®] Centrifuge | Five-minute timer graduated in ten-second intervals Automatic power lamp |
| X SYSTEMS[®] Centrifuge | Refer to the X SYSTEMS [®] Centrifuge Instruction Guide. |

Table 1-1

TD_x Analyzer

| | |
|-----------------------------------|---|
| General Characteristics | |
| Capacity | Carousel 1 to 20 samples |
| Sample Volume | 50 to 500 μ L |
| Carryover | Less than 1.5% at concentrations equal to or greater than the highest calibrator, unless otherwise specified |
| Intensity Stability | Better than 0.1% over the duration of an assay |
| Polarization Range | 0 to 500 mP |
| Physical Characteristics | |
| Size | 22.5" D x 27" W x 13" H (57 cm D x 69 cm W x 33 cm H) |
| Weight | 90 lbs (41 kg) |
| Electrical Characteristics | |
| Voltage | 100, 120, 220, or 240 VAC (+10%, -15%) |
| Frequency | 50 or 60 Hz |
| Power Connection | 3-prong grounded outlet (U.S.) |
| Environmental Requirements | |
| Room Temperature | 15° to 30°C (59° to 86°F) |
| Humidity | 15% to 85% humidity |
| Location | Flat, level surface No direct sunlight or drafts Removed from sources of direct heat and moisture Ventilation space at least 6" on top, sides, and back |
| Optical Characteristics | |
| Light Source | Tungsten halogen lamp, 50 watts, 8 volts |
| Detector | Photomultiplier tube |
| Excitation Peak | 485 nm |
| Excitation Bandwidth | 8 nm |
| Emission Band | 525 to 550 nm |
| RS232 Serial Port | The TD _x analyzer has a 25-pin connector for an RS232 serial communications port. The port uses the echo mode of operation. All run information is printed and sent to the port. For further information, contact the Customer Support Center for the TD _x interface specification. |

Table 1-2

TD_x Centrifuge

NOTE: For the X SYSTEMS™ Centrifuge, refer to the X SYSTEMS Centrifuge Instruction Guide.

| | |
|-----------------------------------|---|
| General Characteristics | |
| Capacity | Head 20 x 1.5 mL tubes |
| Relative Centrifugal Force | 9,500 xg (Minimum) |
| Timer Control | 0-5 minutes |
| Acceleration Time | 6 seconds (full load) |
| BTU/Hr Output | Less than or equal to 450 |
| Physical Characteristics | |
| Size | 11.5" D x 9.25" W x 7.8" H (29.2 cm D x 23.5 cm W x 19.8 cm H) Head Radius 3.05" (7.75 cm) |
| Weight | 13.51 lbs (6.1 kg) |
| Electrical Characteristics | |
| Voltage | 100, 110, or 120 VAC (+10% to -15%) |
| Frequency | 50 or 60 Hz |
| Power Connection | 3-prong grounded outlet (U.S.) |
| Leakage Current | Less than 500 microamps |
| Environmental Requirements | |
| Room Temperature | 15° to 30°C (59° to 86°F) |
| Humidity | 15% to 85% humidity |
| Location | Flat, level surface No direct sunlight or drafts Removed from sources of direct heat and moisture |

Table 1-3

TD_x SSP Cart

| | |
|---------------------------------|--|
| Physical Characteristics | |
| Size | Shelf Up 23"D x 64"W x 36" - 40" H* Shelf Down 23"D x 43.75"W x 36" - 40"H* |
| Weight | 120 lbs (54 kg) |
| | *Cart height is adjustable in 1" increments. |

TD_x System**For *In Vitro* Diagnostic Use**

Components are designed by Abbott Laboratories for optimal performance as a system. Substitution of reagents, accessories, or instrument components may adversely affect performance and may invalidate any warranty agreements.

Abbott Laboratories does not accept responsibility for the accuracy of any assay results produced by the use of reagents, calibrators, controls, disposables, buffer, or pretreatment manufactured by anyone other than Abbott Laboratories.

TD_x Reagents

Do not use reagents beyond their expiration date.

Some reagents contain sodium azide as a preservative; dispose according to accepted guidelines.

To avoid possible contamination, do not combine contents of different reagent packs.

Some reagents contain human blood components. Consider all clinical specimens and reagent controls, calibrators, etc., as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Some reagents contain human urine. Handle with appropriate care.

Do not freeze reagents unless specified; if frozen during shipment, call the Customer Support Center.

Mix by gentle inversion. Avoid excessive agitation to prevent foaming which could affect results. If excessive foaming does occur, allow the reagent pack to set until foam has dissipated.

Do not leave reagent vials uncapped for prolonged periods of time. Immediately following a run, remove reagents from the TD_x analyzer, cap securely and return them to proper storage conditions.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of reagents manufactured by anyone other than Abbott Laboratories.

**TD_x Unit Dose
Reagent Cartridges**

Some reagents contain sodium azide as a preservative; dispose according to accepted guidelines.

Do not use cartridges past their expiration date.

Ensure that the cuvette is securely attached to the unit dose cartridge. To easily attach and prevent breakage of the cuvette, firmly squeeze the cuvette attachment port on the unit dose cartridge with the thumb and forefinger, and release. Attach the cuvette.

Avoid dropping or shaking unit dose cartridges.

Prolonged exposure of individual cartridges to light may be detrimental to assay performance. Store in the light-protective package provided.

Do not puncture foil on cartridge prior to use.

Some reagents contain human blood components. Consider all clinical specimens and reagent controls, calibrators, etc., as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Do not freeze reagents unless specified; if frozen during shipment, call the Customer Support Center.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of reagents manufactured by anyone other than Abbott Laboratories.

Test Sample

Collect blood samples by venipuncture following established good laboratory practices. If the sample is obtained through the infusion set, flush the line thoroughly with saline before taking the blood sample. Refer to the appropriate Sample Collection section of the TD_x/TD_xFL_x® Assays manual for further information.

With some exceptions (noted in the assays manual as a limitation of the procedure), any anticoagulant may be used to collect plasma for analysis. Serum, as well as plasma, may be used for most assays.

It is very important that the physician be informed of the times of sample collection and dose administration; this information should be supplied to the laboratory with each sample and reported with the results of each test.

Samples derived from blood should be refrigerated upon collection and stored frozen (–20°C or colder) if not analyzed within 24 hours. Complete mixing of each thawed sample is required before analysis. For limitations of storage conditions of samples, refer to the appropriate Sample Collection section of the TD_x/TD_xFL_x Assays manual.

Urine samples must be collected in clean, previously unused containers. It is recommended that samples should be refrigerated upon collection and stored frozen (–20°C or colder) if not analyzed within 48 hours. Frozen samples must be thawed and mixed thoroughly prior to analysis. Samples containing particulate matter that does not interfere with the accuracy of the dispensing system, will not adversely affect results.

Cerebrospinal fluid (CSF) and amniotic fluid samples should be obtained using standard collection procedures. For limitations of sample and storage conditions, refer to the appropriate assay under Sample Collection and Preparation for Testing Analysis in the TD_x/TD_xFL_x Assays manual.

Fibrin threads or large particles which could block the probe should not be pipetted or poured into the sample well. After sample transfer, assure there are no bubbles or foam present in the sample well. Remove bubbles or foam prior to running.

Fluorescein is a constituent of all FPIA and REA® reagent systems. Patient samples containing fluorescent compounds may interfere with these TD_x methodologies resulting in high blank intensity readings and low net intensities. If patient samples cannot be diluted below the maximum background value (XX.20) an alternate methodology should be used.

Automatic serum blank readings reduce optical interferences from grossly icteric, hemolyzed or lipemic samples. Serum blanks are automatically subtracted by the TD_x analyzer before final results are printed, when required by the specific assay mode.

No known test method offers complete assurance that human body fluid samples will not transmit infection. Therefore, all clinical specimens should be handled as potentially infectious materials. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Only human samples have been tested and approved for analysis with the TD_x analyzer.

REA is a trademark of Abbott Laboratories.

| | |
|---|--|
| Sample Volume | Most assays require a minimum sample volume of 50 µL. Refer to the assays manual for the specific sample volume. |
| TD_x or X SYSTEMS™ Calibrators, Controls | <p>Some calibrators and controls contain sodium azide as a preservative; dispose according to accepted guidelines.</p> <p>To avoid possible contamination, do not combine contents of different vials.</p> <p>Do not use vials beyond their expiration date.</p> <p>Some calibrators and controls contain human blood components. Consider all clinical specimens and reagent controls, calibrators, etc., as potentially infectious materials. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.</p> <p>Some calibrators and controls contain human urine. Handle with appropriate caution.</p> <p>Abbott Laboratories cannot accept responsibility for the curve stability of any assay performed by use of calibrators and controls manufactured by anyone other than Abbott Laboratories.</p> |
| Storage | All TD _x System products should be stored as described on the product labeling. |
| Disposables: Centrifuge Tubes, Cuvettes, and Sample Cartridges | <p>Ensure all disposables are clean and free of foreign matter before use.</p> <p>Do not wash and reuse centrifuge tubes, cuvettes, or sample cartridges.</p> <p>Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by using centrifuge tubes, cuvettes, or sample cartridges which have been washed for reuse or are manufactured by anyone other than Abbott Laboratories.</p> |
| X SYSTEMS Dilution Buffer | <p>This product contains sodium azide as a preservative; dispose according to accepted guidelines.</p> <p>To avoid possible contamination, do not combine contents of different bottles.</p> <p>Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of dilution buffer manufactured by anyone other than Abbott Laboratories.</p> |

TD_x Pretreatment Procedures

Refer to the appropriate sample collection section in the assays manual for information on the required pretreatment of patient samples for specific assays. The required pretreatment steps for assays are different and must be accurately performed to assure precise results.

Abbott Laboratories cannot accept the responsibility for the accuracy of any assay results produced by use of pretreatment reagents manufactured by anyone other than Abbott Laboratories.

Prevention of Azide Formation in Laboratory Plumbing

Most TD_x/TD_xFL_x[®] reagent products contain sodium azide as a preservative. Sodium azide can form lead or copper azides in laboratory plumbing. These azides may explode on percussion such as hammering on pipes. To prevent formation of lead or copper azide, flush drains thoroughly with water after disposing of solutions containing azide. To remove contamination from old drains suspected of azide accumulation, the following is recommended:

1. Siphon liquid from the trap using a rubber or plastic hose.
 2. Fill the trap with 10% sodium hydroxide solution.
 3. Allow to stand for 16 hours.
 4. Flush well with water.
-

Decontamination Procedures

The TD_x System must be decontaminated prior to contacting the probe/electrode assembly, servicing by Field Service Engineers, or return to Abbott Laboratories.

Probe/Electrode Assembly

Decontaminate the probe/electrode assembly before servicing or removing the probe. Wear gloves, safety glasses and follow other appropriate biosafety practices. Refer to Section V Periodic Maintenance for the Probe Decontamination procedure. This procedure reduces the potential of any infectious organisms being present on the probe/electrode assembly. The 1% sodium hypochlorite solution (20% household bleach) recommended for decontaminating the probe/electrode assembly has been shown to inactivate infectious agents such as HIV and Hepatitis B. Dispose of probe/electrode in an appropriately marked puncture-resistant container.

External Instrument Surfaces

Decontaminate the external surfaces of the instrument by cleaning with a detergent solution to remove any soiling. Then wipe-down with a hospital disinfectant such as 0.5% sodium hypochlorite solution.

Specimens and Disposables

Decontaminate and dispose of all clinical specimens, reagents, controls, calibrators, cuvettes, and other potentially contaminated materials in accordance with local, state and federal regulations governing the treatment of regulated medical waste.

Generally accepted procedures for the treatment of solid, potentially infectious wastes include incineration or autoclaving. If an autoclave is used, the effectiveness of the decontamination cycle should be verified.

Waste Container

Remove the waste container from the instrument before adding disinfectant solution. The addition of a disinfectant to the waste container prior to emptying helps to inactivate infectious organisms that may collect in the waste and thus minimize the risk to personnel who have to handle this material. Sodium hypochlorite and glutaraldehyde solutions have been shown to be effective in inactivating organisms such as HBV, HCV and HIV, and can be used for this purpose. Appropriate personal protective equipment should be worn when these materials are handled.

Do not place the waste container inside the instrument with the disinfectant solution in it.

Empty the waste container and rinse thoroughly with water. Return the container to the proper position.

Do not autoclave the waste container.

Spill Clean-Up

Clean-up spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for clean-up of such spills is to absorb the spill with toweling or other absorbent material, wipe the area with a detergent solution, and then wipe area with an appropriate hospital disinfectant such as 0.5% sodium hypochlorite.

System Components

Do not use bleach solutions to disinfect carousels, tubing, sample syringes, or valve blocks. Degradation of these components or interference with the assays may occur as a result.

References

Biosafety Practices

Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910, 1030. Occupational Exposure to Bloodborne Pathogens; Final Rule. 235: 64175-64182, 1991.

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World Health Organization. Laboratory Biosafety Manual. Geneva. World Health Organization, 1983.

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Centers for Disease Control. Recommendations for Prevention of HIV Transmission in Health Care Settings. MMWR 36, Supplement No. 2S, 1987.

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National Committee for Clinical Laboratory Standards. Clinical Laboratory Hazardous Waste; Proposed Guideline. NCCLS Document GP5-P. Villanova, PA.: NCCLS, 1986.

U.S. Environmental Protection Agency. EPA Guide for Infectious Waste Management. Washington, DC: U.S. Environmental Protection Agency, Publication No. EPA/530-5W-56-014, 1986.

| | |
|---|--|
| TD_x Analyzer | <p>Instrument power should remain on continuously. Refer to the Troubleshooting section for proper start-up procedures following a power interruption.</p> <p>Keep the instrument out of direct sunlight, drafts, and away from sources of direct heat and moisture. Room temperature should be 15° to 30°C (59° to 86°F).</p> <p>Allow adequate ventilation space, at least 6" on top, sides, and back.</p> <p>Keep the access door closed to prevent damage to the air heater and photomultiplier tube.</p> <p>Operate the analyzer on a flat, level surface.</p> <p>Follow recommended maintenance procedures and schedules outlined in Section V, Maintenance.</p> <p>Keep hands away from the syringes, boom assembly and probe while in operation.</p> <p>The lamp, lamp housing, air heater, and liquid heater are hot. Allow these components to cool before servicing.</p> |
| Electrical (TD_x Analyzer) | Follow recommended specifications in this section and installation procedures outlined in Section II. |
| Emergency Shutdown (TD_x Analyzer) | Turn the ON/OFF switch, on the rear panel, to the OFF position. Disconnect the power cord before servicing to prevent electrical shock or damage to the instrument. |
| Results Transmission | <p>Transmissions between the TD_x System and a host computer via the RS232 port may experience interferences from external environmental factors such as static or electromagnetic fields.</p> <p>The following precautions will minimize this risk:</p> <ul style="list-style-type: none"> • High-quality shielded and grounded cable must be used. To ensure integrity of transmissions, the maximum cable length should be limited to 25 feet. • The TD_x System, the host computer, and any associated cables should not be placed near any sources of static or electromagnetic radiation. In particular, proximity to electromagnetic interference sources, such as centrifuges, vortex devices, and their power cords, should be avoided. • Cable connectors must be firmly seated on the TD_x System and the host computer ports and secured with screws. • When you are transmitting data, no error checking information is provided. Results provided through the host computer should be compared with the TD_x printouts for verification of data. <p>Refer to Table 1-1 in Section I for further information on the RS232 port.</p> |

Precision Dispenser

This chemically inert dispenser mechanism can be used for liquids except Hydrofluoric Acid.

TD_x Centrifuge

NOTE: For the X SYSTEMS™ Centrifuge, refer to the X SYSTEMS Centrifuge Instruction Guide.

Do not attempt to defeat the lid interlock system of the centrifuge or operate the unit if the interlock is not functioning. It is there to protect the user.

Do not cover or block the cooling port when the centrifuge is running.

Consider all clinical specimens and reagent controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Decontaminate using a 1% sodium hypochlorite (20% household bleach) solution.

Avoid using excessive amount of water while cleaning. This may cause damage from water seepage around the motor shaft.

Clean any spills that occur in the inner bowl or on top of the unit. Avoid the use of abrasive cleaners which could scratch the surfaces. For safety, unplug the power cord before cleaning any spills.

Some spills could create a biological hazard. Follow approved laboratory procedures when cleaning such spills. Refer to Decontamination Procedures in this section for specific instructions.

If excessive noise or vibration occurs during a run, discontinue the run immediately by rotating the time control to the OFF position. When the lid latch releases, lift the lid and determine the source of the noise or vibration.

If any component of the centrifuge appears to be damaged or if the centrifuge cannot be adjusted to perform properly, discontinue use and contact the Customer Support Center.

Use only X SYSTEMS™ Centrifuge Tubes in the TD_x Centrifuge. Use of any other centrifuge tube may result in damage to the tubes or to the centrifuge itself.

Decontaminate the TD_x Centrifuge prior to shipment.

TD_x Components

Do not use bleach solutions to disinfect the TD_x carousels, tubing, sample syringe or valve block. Degradation of these components or interference with the assays may occur as a result.

Theory of Operation

This portion provides a brief overview of the theory behind the operation of the TD_x System. The TD_x System has become the standard for monitoring therapeutic drug and hormone levels using fluorescence polarization immunoassay (FPIA) technology and competitive binding immunoassay methodology. In addition, the TD_x System uses radiative energy attenuation (REA[®]) technology to perform clinical chemistry assays, and specific antisera and endpoint nephelometry technology to perform Turbo[®] Specific Protein assays (refer to the TD_xFL_x[®] & TD_x Turbo Operation Supplement for further information). More in-depth information may be obtained from your Abbott Sales Representative, or the Customer Support Center (CSC).

Fluorescence Polarization Immunoassay

The TD_x System uses fluorescence polarization immunoassay (FPIA) technology as detailed in the following paragraphs.

The tungsten halogen lamp in the system emits light of different wavelengths or colors with random spatial orientation. An interference filter, located in front of the light source, allows only blue light (481-489 nm) to pass through. The light then passes through a liquid-crystal polarizer to produce plane polarized blue light.

The plane of polarized blue light excites the tracer, or fluorophore, and raises it to an excited state. After excitation, the fluorophore returns to steady state by emitting green light (525-550 nm).

When the fluorophore is bound to a large antibody molecule, it rotates slowly, and the emitted green light is in the same plane as the blue excitation light; polarization is retained. Conversely, when the fluorophore is free it rotates rapidly, and the emitted green light is in a different plane than the blue excitation light; polarization is lost.

Because of the rotational properties of molecules in solution, the degree of polarization is directly proportional to the size of the molecule. Polarization increases as molecular size increases.

**Competitive Binding
Immunoassay**

The TD_x System uses a competitive binding immunoassay methodology to allow tracer-labeled antigen and patient antigen to compete for binding sites on the antibody molecules. The components in this competitive binding reaction are the antibody, the patient antigen, and the antigen labeled with fluorescein (tracer-antigen complex). When competitive binding occurs, the more tracer-antigen complex that binds to the antibody molecule, the less tracer-antigen complex that remains in solution.

If a patient sample contains a low concentration of antigen, after the competitive binding reaction reaches steady-state, there is a high concentration of bound tracer in the reaction mixture and polarization is high. Conversely, if a patient sample contains a high concentration of antigen, after the competitive binding reaction reaches steady-state, there is a low concentration of bound tracer in the reaction mixture and polarization is low. The precise relationship between polarization and concentration of the unlabeled drug or hormone in the sample is established by measuring the polarization values of calibrators with known concentrations of the drug or hormone.

Using the polarization values generated for each sample in the assay, concentrations of drugs or hormones in unknown samples are calculated using the stored calibration curve, and the results are printed out in reportable units.

**Radiative Energy
Attenuation Technology**

Radiative Energy Attenuation (REA[®]) technology applies the fundamental principles of Beer's Law. These principles are used in order to perform analysis of clinical chemistries on the TD_x System.

The measured fluorescence intensity of a solution containing a fluorophore is proportional to the absorbance of the solution. If the solution has an absorbance greater than zero, an attenuation of the fluorescence intensity will be observed. The degree of attenuation will be directly proportional to the absorbance of the solution.

Radiative Energy Attenuation can be used to measure the concentration of specific analytes. When a reagent-analyte reaction generates a chromogen in the presence of a fluorophore, an attenuation of the fluorescence intensity is observed when the chromogen absorbs either the blue fluorophore-excitation or green fluorophore-emission light. If the chromogen absorbs the excitation light only, primary attenuation will be observed. If the chromogen absorbs the emission radiation only, secondary attenuation will be observed. If the chromogen absorbs both the excitation and emission radiation, the total attenuation will be proportional to the sum of the absorbances of the solution at each wavelength. The final fluorescence intensity of the solution will be inversely proportional to the amount of chromogen present in the solution.

Through the use of calibrators, fluorescent intensities can be compared and the analyte concentration in a patient's sample can be calculated. In a sample containing a low concentration of analyte, a small amount of chromogen will be produced, a small amount of light will be absorbed, the attenuation will be small, and the fluorescence intensity will be large. In a sample containing a high concentration of analyte, a large amount of chromogen will be produced, a large amount of light will be absorbed, the attenuation will be large and the fluorescence intensity will be small.

The fluorescence intensity is measured before and after the generation of the chromogen and the percent of light that was not attenuated is calculated. Concentrations of analyte are determined from a previously stored calibration curve and printed in reportable units.

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This section of the manual provides instructions for:


- Unpacking
- Component Installation
- System Initialization
- System Check
- Specification Checks
- Relocation

Follow the Unpacking Instructions that are included with the TD_x System.

Step 1 - Install printer paper and printer ribbon according to the instructions provided in Section V, Maintenance.

Step 2 - Affix labels to the batch and unit dose carousels. For batch, affix a numeric label to the carousel(s) to be used for assay runs and a CAL label to the carousel to be used for calibration runs. For unit dose, affix the UD label to the carousel to be used for assay runs and a CAL label to the carousel to be used for calibration runs. Be sure to place the label carefully in the center of the raised frame area.

Step 3 - Make sure the air-fan filter is clean. If necessary, wash the filter as described in Section V, Maintenance.

Install air-fan filter into the instrument by sliding the filter completely into the bracket under the front of the instrument. See Figure 2.1a. Ensure that the  on the filter handle is right side up.

Check that the air-fan filter is properly seated. Slide the filter into the bracket firmly until it comes to a stop.

Step 4 - Check the outlet voltage to make sure it matches the voltage set on your instrument and that it is within the specification provided in the System Description section. See Figure 2.1b and 2.1c.

CAUTION: IF THE VOLTAGE ON YOUR INSTRUMENT NEEDS TO BE CHANGED, CONTACT THE CUSTOMER SUPPORT CENTER FOR INSTRUCTIONS.

Step 5 - Connect the power cord and turn the power switch to ON.

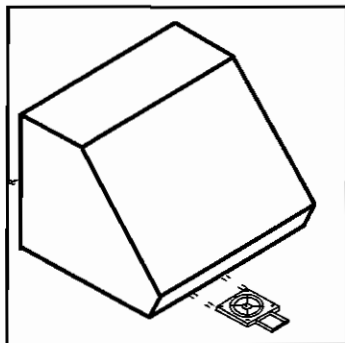


Figure 2.1a

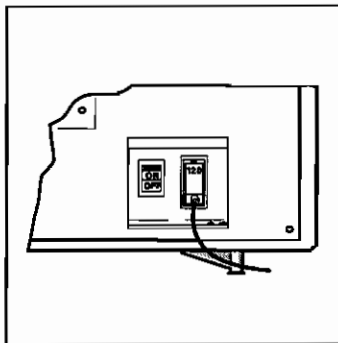


Figure 2.1b

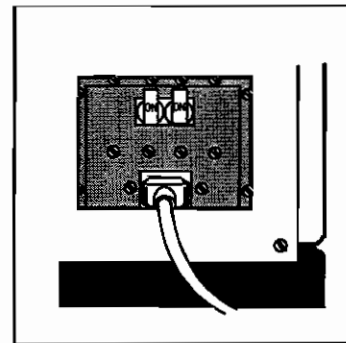


Figure 2.1c

Step 1 - When power is turned on, the display reads:

DATE _____._____._____

Enter the date as follows:

_____._____._____

current current current
month day year

NOTES: Each entry must be two digits and separated by pressing the “.” key. (This character appears in the display as a slash.)

A valid date must be entered.

Step 2 - If the date is entered correctly, press **STORE**. If an entry error is made, press **CLEAR** and repeat step 1. When the date is stored, the following display reads:

TIME _____._____._____

Step 3 - Enter the time using military (24-hour) time as follows:

_____._____._____

current current current
hour minute second

NOTES: Each entry must be in two digits and separated by pressing the “.” key. This will appear in the display as a colon.

Step 4 - If the time is entered correctly, press **STORE**. If an entry error is made, press **CLEAR** and repeat step 3.

After power-up, the TD_x System begins a maximum 5-minute warm-up period. After the warm-up period, the display panel reads:

READY

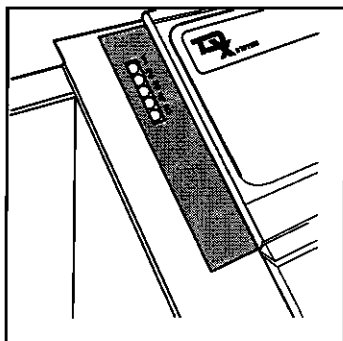


Figure 2.2

Step 1 - Remove the buffer panel and verify that the five power supply lights are illuminated. See Figure 2.2. (Refer to Section VI, Troubleshooting, under Observed Problems if a light is not on.)

Step 2 - Install the buffer bottle and prime the instrument five times to remove any air bubbles. (Refer to Section VI, Troubleshooting, under Observed Problems for corrective action, if air bubbles remain in the dispenser.)

Step 3 - Press **SYSTM 2 PRINT** to print the System Control parameters. Verify that the parameters are the same as the printout received with your unit. If they do not agree, edit the parameters to match those on the printout. (Refer to Section I, System Description, under Summary of Keypad Functions for editing procedures.)

Step 4 - Press **SYSTM 3 PRINT** to print the System parameters. Verify that the parameters are the same as the printout received with your unit. If they do not agree, edit to match the parameters on the printout. (Refer to Section I, System Description, under Summary of Keypad Functions for editing procedures.)

Step 5 - Press **SYSTM 6 PRINT** to print Identification parameters.

Step 6 - Press **SYSTM 8 PRINT** to print the unit dose parameters. Verify that the parameters are the same as the printout received with your unit. If they do not agree, edit to match the parameters on the printout. (Refer to Section I, System Description, under Summary of Keypad Functions for editing procedures.)

Step 7 - Press **SYSTM 9 PRINT** to print Shared Pack options. Verify that these parameters are set at 0. If you wish to use these options, edit to 0 or 1 for the specific assay you select. (Refer to System 9 - Shared Pack Options in the Diagnostic Checks section for specific information.)

Step 8 - Allow the TD_x System to warm up for 30 minutes before performing any specification checks to avoid any heater error messages.

The following steps should be performed prior to operation. The instructions for Steps 1–5 can be found in Section V, Maintenance, unless otherwise noted.

Step 1 - Perform the Daily Start-Up Procedures.

Step 2 - Perform a Temperature Check (Test 2.1).

Step 3 - Perform a Photo Calibration* (Test 3.4).

Step 4 - Perform a Photo Check (Test 2.2).

Step 5 - Perform a Pipet Check (Test 2.3).

Step 6 - Edit the LOLIM assay parameters for each assay, if desired (press **ASSAY XX.3 EDIT**, enter low limit therapeutic range, press **STORE STOP**). For Abused Drug assays only, parameter XX.3, LOLIM, will read BKG FAC. Refer to Section III, Operation, Assay Parameters.

Step 7 - Edit the HILIM assay parameters for each assay, if desired (press **ASSAY XX.4 EDIT**, enter high limit therapeutic range, press **STORE STOP**). For Abused Drug assays only, parameter XX.4, HILIM, will read THRSHLD. Refer to Section III, Operation, Assay Parameters.

Step 8 - Edit the following system parameters, if desired:

RST SPL - controls automatic resetting of the sample volume following a dilution protocol assay. This system parameter is not operable for HDL Cholesterol, CRP, or any unit dose assays.

NOTE: Specific Proteins assays run in the unit dose mode. However, RST SPL is available for these assays.

To activate RST SPL, press **SYSTEM 2.3 EDIT 1 STORE STOP**.

OP ID - controls the option of programming the TD_x System to prompt for an operator ID number at the beginning of each assay and calibration run. To activate press **SYSTEM 6.3 EDIT 1 STORE STOP**.

*Refer to Section IV, Diagnostic Checks for the procedure.

RGT LOT - controls the option of programming the TD_x System to prompt for a reagent lot number at the beginning of each batch assay and calibration run. To activate press **SYSTEM 6.5 EDIT 1 STORE STOP**.

PAT ID - controls the option of programming the TD_x System to prompt for a patient ID number for each sample, at the beginning of each batch assay run. To activate press **SYSTEM 6.6 EDIT 1 STORE STOP**.

T PRINT - controls the type of printout for Abused Drug assays only. It is automatically set to 1. To change press **SYSTEM 6.7 EDIT 0 STORE STOP**. For more details on T Print (System 6.7) refer to Section III, Operation, under Batch Calibration and Assay Procedures.

For Thyroid features (System 7.1 through System 7.5) refer to the T-Uptake assay insert in the assays manual.

Step 9 - Run Calibration curves for the assays to be performed.

Step 10 - Complete and return the Installation Report.

If after the initial installation it becomes necessary for you to relocate the TD_x System, ensure that the new location accommodates all electrical and environmental specifications. See Table 1-1 in the System Description section for specifications.

1. Turn the power switch to OFF and disconnect the power cord.
2. Before moving the instrument, gently swing the boom arm so that the probe tip rests above the waste cup opening.
3. Gently lower the probe tip into the opening, but do not touch the bottom of the waste cup. This protects the probe from possible damage.
4. Reconnect the power cord and turn the power to ON.
5. Initialize the TD_x System as described in this section. If power to the TD_x System is interrupted for more than 30 minutes, the TD_x System should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.

Prior to operation, perform a Photo Check (Test 2.2).

When initiating the first assay run, validate one level of control (H, M or L) for the reagent system being used. If the control is out of range, call the Customer Support Center for further instructions.

If the TD_x System is being moved from one laboratory to another, and the printed circuit board retainers have been previously removed, reseal the printed circuit boards as described in Section V, Component Replacement, Circuit Board Removal and Replacement.

Introduction

This section provides details on the following information:

- Quality Control
- Daily Startup
- Assay Listing
- Assay Parameters
 - Listing
 - Explanation
 - Editing
- Changing Concentration Units
- Batch Calibration Procedure
- Unit Dose Calibration Procedure
- Calibration Overview
 - Instrument calibration criteria
 - Verifying calibration acceptability
 - When to recalibrate
- Batch Assay Procedure
- Unit Dose Assay Procedure
- Dilution Protocol
- Barcode Override
 - Batch
 - Unit Dose
- TD_x Centrifuge Operation

Quality Control

Quality control procedures recommended to ensure optimal assay and instrument performance include:

1. Performing all maintenance procedures presented in Section 5.0 Maintenance.
2. Verifying quality control requirements in the assay specific insert.

Daily Startup

These procedures should be performed at the start of each day. If the system is used on multiple shifts, perform the procedures at the start of each 8-hour shift.

1. Waste Container - Empty and wash the container and return it to its proper position.
2. Probe Inspection and Wash (Section V).
3. Dispense Assembly Inspection
Remove the dispense cover.
PRIME three times.

Inspect for air bubbles and leaks in all tubing, syringes, and connections. (To remove air bubbles, refer to Section VI, under Observed Problems).

Inspect for dried buffer salts or liquid buffer in and around all dispenser components. Replace as needed.
4. Unit Dose Probe Position - Verify probe position daily at the completion of a run. If the puncture marks in the foil are not correct, refer to Section V for unit dose probe positioning.
5. Maintenance Log - Make appropriate entries.

Listing of Assays

A list of assays in TD_x memory can be obtained by pressing **ASSAY PRINT**. The instrument prints the list of assays and their numbers. Retain this list to avoid the need to perform this step each time an assay number is required.

Listing Assay Parameters

To list the parameters for an assay, use this procedure:

1. Determine the assay number from the assay list.
2. Press **ASSAY XX PRINT**, with XX being the assay number. The analyzer prints the parameters for the selected assay. These 23 parameters set the specific characteristics of each individual assay. An explanation of these parameters follows.
3. Check the parameters on the printout against the parameters listed in the description of the assay in the assays manual insert or kit enclosure update. Ensure that the parameters are identical.

NOTE: Information contained in a kit enclosure (activation letter, important note, etc.) **always** supersedes assay manual inserts.

4. If the parameters match, proceed with the assay. If the parameters do not match, edit the instrument parameters to match those in the assay insert or kit enclosure.

Explanation of Assay Parameters

The following lists and defines assay parameters:

| | |
|--------------|--|
| .1 SPL VOL*- | Final volume of sample in cuvette in microliters. |
| .2 SPL REP- | Sample replication 1-20. (If SPL REP is programmed to a value greater than 1, the TD _x System prints an average of the replicates, in addition to each individual sample value.) This parameter does not apply to unit dose assay runs. |
| .3 LOLIM**- | Low concentration for flagging samples below therapeutic or normal range. For abused drug assays, this parameter is the BKG FAC. |
| .4 HILIM**- | High concentration for flagging samples above therapeutic or normal range. For abused drug assays, this parameter is the THRSHLD concentration. |
| .5 CAL VOL*- | Final volume of calibrator in cuvette in microliters. |
| .6 CAL REP- | Calibrator replicates (1-3). |
| .7 CONC A- | A Calibrator concentration. |
| .8 CONC B- | B Calibrator concentration. |
| .9 CONC C- | C Calibrator concentration. |
| .10 CONC D- | D Calibrator concentration. |
| .11 CONC E- | E Calibrator concentration. |
| .12 CONC F- | F Calibrator concentration. |

* Values for SPL VOL and CAL VOL are equal for most assays. See the assays manual for specific assay parameters.

** LOLIM and HILIM values can be edited to acceptable therapeutic or normal range values for each assay. Concentration results are flagged as **LOW** or **HI** if they fall outside these programmed values.

.13 UNITS-

Code for concentration units. The following units are available by code number:

| <u>Code</u> | <u>Unit</u> | <u>Definition</u> |
|-------------|----------------|---------------------------|
| 0 | µg/mL | Micrograms/Milliliter |
| 1 | ng/mL | Nanograms/Milliliter |
| 2 | µmol/L | Micromoles/Liter |
| 3 | nmol/L | Nanomoles/Liter |
| 4 | mmol/L | Millimoles/Liter |
| 5 | mol/L | Moles/Liter |
| 6 | µg/dL | Micrograms/Deciliter |
| 7 | mg/dL | Milligrams/Deciliter |
| 8 | g/dL | Grams/Deciliter |
| 9 | g/L | Grams/Liter |
| 10 | mEq/L | Milliequivalents/Liter |
| 11 | Units/L | Units/Liter |
| 12 | mUnits/µL | Milliunits/Microliter |
| 13 | I Units/L | International Units/Liter |
| 14 | % | Percentage |
| 15 | mg/L | Milligrams/Liter |
| 16 | T-Uptake Units | T-Uptake Units |
| 17 | (user defined) | User Defined Units |
| 18 | mP | Millipolarization Units |
| 19 | mg/g | Milligrams/Gram |

.14 CRV FIT-

Data reduction for calibration curve (2 through 21).

.15 MX DEV-

Maximum range of millipolarization values or percent fluorescence intensities allowed on calibrator replicates.

| | |
|-----------------|---|
| .16 MN POLA***- | Minimum millipolarization allowed for the A calibrator during a calibration. |
| .17 MN SPAN- | Minimum millipolarization or percent fluorescence intensity span allowed between A and F calibrators during a calibration. |
| .18 MODE- | Pipetting sequence. |
| .19 GAIN***- | Relative value to set PMT voltage. |
| .20 MX BKG- | Maximum background intensity allowed before flagging occurs. For abused drug assays, if parameter .3 BKG FAC is edited or whenever a pipette check is performed, then $\text{MX BKG} (.20) = \text{BKG FAC} (.3) \times \text{MN TR} (.21)$. |
| .21 MN TR***- | Minimum allowed net intensity reading before flagging occurs. (This parameter automatically updates when a Pipet Check procedure is run.) |
| .22 C DATE***- | Date of last batch calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.) |
| .23 C TIME***- | Time of last batch calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.) |

***These parameters cannot be edited. If an attempt is made to edit them, the message [WRT PROTECT] appears in the display. Press **STOP** to continue operation.

Editing Assay Parameters

1. To edit an assay parameter, select the assay number and the number of the parameter to be changed. For example, 4.1 is the parameter for sample volume for Phenytoin.
2. Press **ASSAY XX.X EDIT** (enter the new parameter value) **STORE**.
3. If another parameter is to be edited for the same assay, press **NEXT** until the parameter to be edited is in the display, (enter the new parameter value), press **STORE**.
4. After editing is complete, press **STOP**. Then press **ASSAY XX.X PRINT**, to get a printout of the specific new assay parameter value or **ASSAY XX PRINT** to obtain a complete listing of all parameters. Check that the new parameter values are appropriate for the assay.

Changing Concentration Units

To report results in concentration units other than the units listed on the package of calibrators for that assay, the following changes must be made to the assay parameters:

1. Edit the units to the desired concentration by using the code number designated in assay parameter (.13). This only changes the units of concentration that print on the header.
2. Mathematically convert the concentration of each calibrator (B through F) to the new units of concentration.

Example: To convert from $\mu\text{g/mL}$ to $\mu\text{M/L}$ calculate the following:

$$\frac{(\text{conc. in } \mu\text{g/mL}) (1000 \text{ mL/L})}{\text{molecular weight}} = \mu\text{M/L}$$

3. Edit the new concentration for each calibrator into assay parameters (.8) through (.12). Edit the LOLIM (.3) and HILIM (.4) parameters. For abused drug assays, LOLIM (.3) = *BKG FAC and HILIM (.4) = THRSILD.

*Do not edit for abused drug assays. The BKG FAC is used with the MN TR (.21) to calculate an instrument specific MX BKG (.20).

4. Calibrate the assay.

NOTE: Concentration units for some assays cannot be changed. Refer to the specific assay procedure section in the assay manual insert.

Introduction

The following paragraphs present the step-by-step procedure for performing a batch calibration run.

Before you begin:

- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to Section V, Maintenance.
 - Ensure that assay parameter .6 CAL REPS is 2. Press **ASSAY XX.6 DISPLY**. If 2, press **STOP**, if not, press **EDIT 2 STORE STOP**.
 - If running an abused drug assay calibration, ensure the numerical print option (T Print, System 6.7 =0) has been selected. Press **SYSTM 6.7 DISPLY**. If 0, press **STOP**, if not, press **EDIT 0 STORE STOP**. This allows the system to print numerical values for control samples; thus allowing verification of calibration acceptability as outlined in the Calibration Overview section.
 - If pretreatment of calibrators and controls is required, follow the pretreatment procedure as described in the appropriate assay insert in the assays manual.
-

Preparing the Carousel

1. Select a calibration carousel.
2. Load 15* sample cartridges and cuvettes. Begin with Position 1 and continue sequentially. Do not skip a position. Ensure that all cuvettes are right side up. Ensure that all disposables are clean and free of foreign matter before use.
3. Lock cuvettes into position by turning the locking mechanism clockwise until it clicks.
4. Invert the calibrator pack gently five times. Pipette, in duplicate, the appropriate volume** of calibrators A through F into sample wells 1 through 12. Avoid splashing, foaming, or bubbling.

Example: Pipette calibrator A into positions 1 and 2, B into 3 and 4, C into 5 and 6, etc.

Recap each calibrator vial as it is used, and return the pack to proper storage as described on the labeling.

* For some assays, only 14 sample cartridges and cuvettes are required, as there are only two controls (H and L).

** For most assays 50 µL sample volume is sufficient; refer to the assays manual for the specific sample volume.

-
5. Invert the control pack gently five times. Pipette the appropriate volume* of H, M, and L controls into sample wells 13 through 15. Avoid splashing, foaming, or bubbling. Positions 16 through 20 are available for patient samples.

NOTE: If the Display Data option (System 4.2) is being used, do not run any samples (unknowns or controls) after the last calibrator. They will not appear in the display and the results cannot be retrieved.

For some assays, do not run controls on the calibration run. No results will be printed for the controls. Refer to the specific assays procedure in the assays manual.

Recap each control vial as it is used and return the pack to proper storage as described on the labeling.

6. Inspect the surface of the sample wells for bubbles and remove with applicator sticks. (Use a different applicator stick for each level of calibrator or control.)
-

Preparing the Reagent Pack

7. Select the appropriate reagent pack.
 8. Invert gently five times.
 9. Open the reagent pack and check to be sure the vials read **S, T, P**.
NOTE: T-Uptake vials read **P, T, P**. 4-pot reagent pack vials read **W, S, T, P**.
 10. Remove the vial caps and place them upside-down in the lid spaces provided.
 11. Inspect the surface of the liquid in the vials for bubbles and remove any bubbles with applicator sticks. (Use a different applicator stick for each vial.)
-

Run Calibration

12. Insert the reagent pack into the proper position in the analyzer.
13. Place the loaded calibration carousel into the instrument. Close the access door.
14. Press **RUN**.
15. If your instrument is not programmed to record the operator ID, go to step 16. If it is programmed to record this number, the display reads:

OP ID?

Enter your ID number and press **STORE**.

* For most assays 50 μ L sample volume is sufficient; refer to the assays manual for the specific sample volume.

16. If your instrument is not programmed to record the reagent lot number, go to step 17. If it is programmed to record this number, the display reads:

RGT #?

Enter the reagent lot number and press **STORE**.

17. Verify that the correct assay name and the word [CALIBRATION] displays before leaving the analyzer. If the assay name displayed is incorrect, press **STOP** and refer to the barcode override procedure in this section.
18. The observed data and the calculated curve print at the end of the run. Do not press **STOP** before the printout is complete. Doing so terminates processing and prevents storage of the calibration curve. When calibration is complete, the instrument displays:

DONE - REMOVE RPAK

Clean-Up

19. If the reagent pack is not to be used **immediately**, it should be removed, recapped, and returned to proper storage as described on the labeling.

20. Remove the carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

CAUTION: IF SPLASHING OR FOAMING IS OBSERVED, DO NOT REPORT RESULTS. THESE SYMPTOMS INDICATE A PROBLEM AND REQUIRE CORRECTIVE ACTION. REFER TO SECTION VI, UNDER OBSERVED PROBLEMS.

21. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to Decontamination Procedures in Section I, under Operational Precautions and Limitations.

If separation of plastic and glass is not required, unlock the carousel, invert over a receptacle and discard the cartridges and cuvettes all at once. Ensure that all sample cartridges and cuvettes have been removed.

If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle and discard the cuvettes. Ensure that all sample cartridges and cuvettes have been removed.

22. Verify the calibration acceptability (refer to Calibration Overview in this section).

NOTE: During a calibration run (batch or unit dose), if an LLS FAIL occurs in the first unknown position, neither the unknown header or the unknown results are printed.

Reading a Therapeutic Drug or Hormone Batch Calibration Printout

The following printout is typical of a therapeutic drug
or hormone calibration.

A

DATE:

B

TIME:

C

SERIAL #:

D

LOCK = 1

E

OP ID #:

F

RGT LOT #:

G

ASSAY: THEOPHYLLINE

CALIBRATION

H

VOL = 2.00

I

REPS = 2

J

GAIN = 40

K

CONC = UG/ML

L

| I.D. | NET P | NET I | BLANK I |
|------|--------|---------|---------|
| 1 A | 242.39 | 7105.84 | 460.6 |
| 2 A | 244.11 | 7488.64 | 452.9 |
| 3 B | 217.79 | 7276.94 | 472.1 |
| 4 B | 217.11 | 7276.94 | 472.1 |
| 5 C | 196.02 | 7551.34 | 419.3 |
| 6 C | 196.99 | 7323.04 | 422.9 |
| 7 D | 169.24 | 7572.54 | 433.4 |
| 8 D | 167.98 | 7654.14 | 431.1 |
| 9 E | 135.77 | 7871.24 | 440.7 |
| 10 E | 135.06 | 7776.14 | 448.0 |
| 11 F | 101.86 | 8023.64 | 444.8 |
| 12 F | 102.31 | 8096.44 | 452.1 |

| I.D. | CONC | AVGP | FITP | PERR |
|------|-------|--------|--------|-------|
| A | 0.00 | 243.25 | 243.25 | 0.00 |
| B | 2.50 | 217.45 | 216.80 | 0.65 |
| C | 5.00 | 196.51 | 197.09 | -0.58 |
| D | 10.00 | 168.61 | 168.80 | -0.19 |
| E | 20.00 | 135.42 | 134.95 | 0.47 |
| F | 40.00 | 102.09 | 102.27 | -0.18 |

T

RMSE = 0.36

SAMPLES

LOC

CONC

NET P

BLK I

13

7.32 LOW

182.49

433.40

14

12.22

159.30

427.96

15

25.20 HI

123.57

427.91

U

- A. date of calibration
- B. time of calibration
- C. serial number of instrument
- D. door lock status - 0 = off, 1 = on
- E. operator ID number (optional feature)
- F. reagent lot number (optional feature)
- G. name of assay being calibrated
- H. volume - final amount of calibrator in cuvette
- I. number of calibrator replicates
- J. gain
- K. concentration units
- L. position of calibrators in carousel
- M. blank intensity - calibrator background intensity
- N. net intensity - fluorescence intensity readings after tracer has been added and correction for background readings made
- O. net polarization - net intensity readings calculated as a polarization value
- P. expected concentrations of calibrators
- Q. average polarization - the average of the net polarizations calculated for each replicated calibrator
- R. fit polarization - the polarization values obtained when the calibration curve is fitted as close as possible to the average polarizations calculated
- S. polarization error - calculated as the average polarization (AVGP) for each calibrator minus the fit polarization (FITP) for each calibrator
- T. Root Mean Square Error - a measurement of standard deviation of the PERRs
- U. concentrations, net polarizations, and blank intensity readings of the control samples

Reading Clinical Chemistry Calibration Printouts

A printout for a clinical chemistry calibration is very similar to a therapeutic drug or hormone batch calibration printout. Some column headings differ, as shown in the printout below.

| DATE: | | | | |
|---|-----------|----------|-----------|-------|
| TIME: | | | | |
| SERIAL #: | | | | |
| LOCK = 1 | | | | |
| ASSAY: GLUCOSE | | | | |
| CALIBRATION | | | | |
| VOL = 3.00 | | | | |
| REPS = 2 | | | | |
| GAIN = 5 | | | | |
| CONC = MG/DL | | | | |
| <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">A</div> <div style="text-align: center;">B</div> <div style="text-align: center;">C</div> </div> | | | | |
| I.D. | PERCENT | FINAL V | INITIAL V | |
| 1 A | 93.33 | 10388.31 | 11130.4 | |
| 2 A | 95.10 | 10598.61 | 11144.7 | |
| 3 B | 67.15 | 7381.81 | 10993.5 | |
| 4 B | 66.14 | 7353.41 | 11118.6 | |
| 5 C | 46.96 | 5176.81 | 11023.6 | |
| 6 C | 46.28 | 5154.71 | 11138.9 | |
| 7 D | 33.63 | 3707.31 | 11022.2 | |
| 8 D | 33.65 | 3716.11 | 11043.2 | |
| 9 E | 23.58 | 2642.81 | 11208.1 | |
| 10 E | 24.14 | 2635.41 | 10915.9 | |
| 11 F | 17.62 | 1964.51 | 11146.2 | |
| 12 F | 17.03 | 1893.11 | 11113.5 | |
| <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">D</div> <div style="text-align: center;">E</div> <div style="text-align: center;">F</div> </div> | | | | |
| I.D. | CONC | AVG | FIT | ERR |
| A | 0.00 | 94.22 | 94.22 | 0.00 |
| B | 100.00 | 66.64 | 66.61 | 0.03 |
| C | 200.00 | 46.62 | 46.74 | -0.12 |
| D | 300.00 | 33.64 | 33.40 | 0.24 |
| E | 400.00 | 23.86 | 24.07 | -0.21 |
| F | 500.00 | 17.33 | 17.26 | 0.07 |
| RMSE = 0.12 | | | | |
| SAMPLES | | | | |
| LOC | CONC | PERCENT | FINAL V | |
| 13 | 253.36 HI | 39.00 | 4385.69 | |
| 14 | 110.23 HI | 64.18 | 7179.25 | |
| 15 | 72.65 | 73.60 | 8064.64 | |

- A. percentage of blue and green light not absorbed by the chromogen in calibrators
- B. final vertical intensity readings of the calibrators
- C. initial vertical intensity readings of the calibrators
- D. average of percent readings — the average of the percent readings for each replicated calibrator
- E. fit percent readings
- F. error — calculated as the average percent reading minus the fit percent reading
- G. patient concentrations, percent of light not absorbed by the chromogen, and final vertical intensity readings of the control samples

Reading an Abused Drug Calibration Printout

This printout is similar to a therapeutic drug or hormone batch calibration printout (exceptions noted). This example was obtained with System 6.7 (T Print) set to 0.

DATE:
TIME:

SERIAL #:
LOCK = 1
ASSAY: AMPHET/METH U **C**

CALIBRATION

VOL = 8.00
REPS = 2
GAIN = 20

CONC = NG/ML

| I.D. | NET P | NET I | BLANK I |
|------|--------|--------|---------|
| 1 A | 211.25 | 4776.2 | 596.4 |
| 2 A | 210.96 | 4972.2 | 611.6 |
| 3 B | 194.98 | 4972.6 | 490.0 |
| 4 B | 193.26 | 4961.7 | 496.5 |
| 5 C | 183.96 | 5045.7 | 461.8 |
| 6 C | 183.85 | 4990.7 | 468.8 |
| 7 D | 165.65 | 5038.6 | 468.5 |
| 8 D | 166.12 | 5055.3 | 462.5 |
| 9 E | 150.14 | 5179.4 | 629.2 |
| 10 E | 149.10 | 5070.8 | 620.3 |
| 11 F | 135.84 | 5243.6 | 615.7 |
| 12 F | 134.99 | 5292.6 | 624.9 |

| I.D. | CONC | AVG P | FITP | PERR |
|------|---------|--------|--------|-------|
| A | 0.00 | 211.11 | 211.11 | 0.00 |
| B | 150.00 | 194.12 | 194.14 | -0.02 |
| C | 300.00 | 183.91 | 184.00 | -0.09 |
| D | 1000.00 | 165.89 | 165.61 | 0.28 |
| E | 3000.00 | 149.62 | 149.89 | -0.27 |
| F | 8000.00 | 135.42 | 135.33 | 0.09 |

RMSE = 0.14 **A**

STORED THRESHOLD = 300.00

| LOC | SAMPLES CONC | NET P | BLK I |
|---------------|-----------------|--------|--------|
| B { 13 | 610.00 >= T | 170.12 | 511.06 |
| 14 | 1880.00 >= T | 144.86 | 510.59 |

- A. - same value as assay parameter .4 (THRSHLD).
 B. >= T - indicates concentration is greater than or equal to the threshold.
 C. U - indicates a urine assay.

The following paragraphs explain the print options available for an abused drug calibration printout using different System 6.7 settings:

SYSTEM 6.7 = 0

- If SYSTM 6.7 = 0, the printout is similar to a therapeutic drug or hormone batch calibration printout, except that $\geq T$ (greater than or equal to threshold) prints following numerical results above the stored threshold.
-

SYSTEM 6.7 = 1

- If SYSTM 6.7 = 1, then \geq THRESHOLD or NONE DETECTED prints in place of a numerical result.
- If SYSTM 6.7 = 1, a numerical result may be obtained by editing System 6.7 to 0 and reprinting the calibration curve data by pressing **SYSTM 4.1 RUN**. Reprint must be performed before any further operations are initiated on the TD_x analyzer; otherwise, the calibration and control data will not be available for retrieval.

Introduction

The TD_x System stores a calibration curve for each unit dose assay that is separate and distinct from the calibration curve stored for the batch version of the same assay. Therefore, prior to running a unit dose assay, the instrument must be calibrated for that assay in the unit dose mode, even if that assay has already been calibrated in the batch mode.

The procedure for unit dose calibration is virtually identical to the batch procedure except that single replicate calibration is allowed. The Cal Reps (assay parameter .6) must be set to 1 when running a single replicate calibration; edit to 2 if duplicate calibration is desired. The unit dose calibration single replicate procedure is as follows:

- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to Section V, Maintenance.
- Ensure that assay parameter .6 CAL REPS is 1. Press **ASSAY XX.6 DISPLY**. If 1, press **STOP**, if not, press **EDIT 1 STORE STOP**.

Preparing the Carousel

1. Select the unit dose calibration carousel. Visually inspect the foil seals on the reagent wells of the cartridge for signs of leakage (a flaky white powder around the edges of the foil). Do not use any cartridge that appears to have leaked. For more information, contact the Customer Support Center.
2. Attach cuvettes to 9 unit dose cartridges for the assay being calibrated. Ensure that all disposables are clean and free of foreign matter before use. To easily attach and prevent breakage of the cuvette, firmly squeeze the cuvette attachment port on the unit dose cartridge with the thumb and forefinger, and release. Attach the cuvette. Insert the cartridges into positions 1 through 9.

NOTE: For calibration, use only cartridges of the same lot number.

3. Lock the carousel by turning the locking mechanism clockwise until it clicks.
4. Invert the calibrator pack gently five times. Pipette the appropriate volume* of Calibrators A through F into the sample wells of the unit dose cartridges in positions 1 through 6 (Calibrator A in position 1, B in 2, etc.). Avoid splashing, foaming, or bubbling. Recap calibrator vials as used and return pack to proper storage, as described on the labeling.
5. Invert control pack gently five times. Pipette the appropriate volume* of H, M, and L controls into the sample wells of cartridges 7 through 9. Avoid splashing, foaming, or bubbling. Recap control vials as used and return pack to proper storage, as described on the labeling. Positions 10-20 are available for patient samples. Patient samples must be for the assay being calibrated.
6. Inspect the samples for bubbles and remove any bubbles with applicator sticks. (Use a different applicator stick for each level of calibrator or control.)
7. Place the unit dose calibration carousel into the instrument and close the access door.

* For most assays 50 μ L sample volume is sufficient; refer to the assays manual for the specific sample volume.

Run Calibration

8. Press **RUN**.
9. If your instrument is not programmed to record the operator ID go to step 10. If it is programmed to record this number, the display reads:

OP ID?

Enter your ID number and press **STORE**.

NOTE: Reagent lot numbers and patient ID numbers cannot be entered in the unit dose mode of operation.

10. The system reads the barcode on the unit dose calibration carousel and then displays:

UNIT DOSE CALIB

The system then reads the barcode on each cartridge to verify the assay being calibrated. Calibration then begins. If the assay name displayed is incorrect, press **STOP** and refer to the Barcode Override procedure in this section.

11. The observed data and the calculated curve print at the end of the run. Do not press **STOP** before the printout is complete. Doing so terminates processing and prevents storage of the calibration curve. When calibration is complete, the instrument displays:

ASSAY COMPLETE

then,

READY

Clean-Up

12. Remove the carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

CAUTION: IF SPLASHING OR FOAMING IS OBSERVED, DO NOT REPORT RESULTS. THESE SYMPTOMS INDICATE A PROBLEM AND REQUIRE CORRECTIVE ACTION. REFER TO SECTION VI, UNDER OBSERVED PROBLEMS.

13. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to Decontamination Procedures in Section I, under Operational Precautions and Limitations.

If separation of plastic and glass is not required, unlock the carousel, remove the cartridge with cuvette attached, and discard into a receptacle.

If separation of glass and plastic is required, unlock the carousel and remove the cartridge with cuvette attached. Detach cuvette and discard in glass disposal. Discard the cartridge into its proper receptacle.

14. Verify the calibration acceptability (refer to Calibration Overview in this section).
15. Edit the CAL REPS back to 2 prior to performing a batch calibration. Press **ASSAY X.6 EDIT 2 STORE STOP**.

Reading Unit Dose Calibration Printouts

A printout for a unit dose calibration is the same as for the batch calibration printout except that UNIT DOSE CALIBRATION prints before the date and no reagent lot number is allowed.

| | | | | |
|-----------------------|----------|----------|------------|-------|
| UNIT DOSE CALIBRATION | | | | |
| DATE: | | | | |
| TIME: | | | | |
| SERIAL #: | | | | |
| LOCK = 1 | | | | |
| OP ID #: | | | | |
| ASSAY: NAPA | | | | |
| CALIBRATION | | | | |
| VOL = 2.00 | | | | |
| REPS = 1 | | | | |
| GAIN = 30 | | | | |
| CONC = UG/ML | | | | |
| I.D. | NET P | NET I | BLANK I | |
| 1 A | 236.39 | 3298.04 | 467.7 | |
| 2 B | 206.95 | 3102.34 | 418.3 | |
| 3 C | 170.57 | 3212.24 | 413.5 | |
| 4 D | 146.81 | 3272.54 | 478.1 | |
| 5 E | 131.17 | 3377.84 | 420.3 | |
| 6 F | 112.24 | 3465.24 | 478.2 | |
| I.D. | CONC | AVGP | FITP | PERR |
| A | 0.00 | 236.39 | 236.39 | 0.00 |
| B | 2.00 | 206.95 | 205.89 | 1.06 |
| C | 6.00 | 170.57 | 172.49 | -1.92 |
| D | 12.00 | 146.81 | 145.79 | 1.02 |
| E | 18.00 | 131.17 | 130.36 | 0.81 |
| F | 30.00 | 112.24 | 112.94 | -0.70 |
| RMSE = 0.94 | | | | |
| SAMPLES | | | | |
| LOC | CONC | NET P | BLK I | |
| 7 | 23.97 HI | 120.23 | 468.99 | |
| 8 | 9.62 | 154.42 | 418.86 | |
| 9 | 4.49 LOW | 182.76 | 435.37 | |

Instrument Calibration Criteria

Before the microprocessor performs the curve fit routine, the raw data from the calibrators are verified as listed below to be sure the criteria are met. When a curve fit criterion is not met, an error message prints on the result tape and the curve is not stored. Any remaining checks are not performed.

1. Correct number of replicate samples of calibrators (six times assay parameter .6 CAL REPS). CALIBRATION ABORTED, CAL REPS INCORRECT FOR CALIBRATION.
2. Background fluorescence intensity (BLK I) (less than or equal to assay parameter .20 MX BKG). BACKGROUND TOO LARGE.
3. Net fluorescence intensity (NET I) (equal to or greater than assay parameter .21 MN TR). NET I TOO SMALL.
Net fluorescence intensity (NET I) (less than 25.5 times assay parameter .21 MN TR). NET I LARGE.
4. Reproducibility of calibrator replicates within specified range of mP or percent fluorescence intensity (assay parameter .15 MX DEV) when run in duplicate or triplicate. RANGE TOO LARGE.
5. Polarization of calibrator A (equal to or greater than assay parameter .16 MN POLA). P 0 TOO SMALL. (For T-Uptake, this specification applies to the F calibrator.)
6. Difference in polarization or percent fluorescence intensity between the A and F calibrators (equal to or greater than assay parameter .17 MN SPAN). SPAN LESS THAN MIN SPAN. (For some assays the span between A and B, B and C, C and D, D and E, and E and F are checked. A check is also made to ensure the millipolarization of the A calibrator does not exceed the programmed quality control value.
The analyzer indicates these span differences as CRV FIT XXX, with XXX signifying a number. Definition of this CRV FIT # is in Section VI, Troubleshooting, under Printed Error Codes.

7. Polarization or percent fluorescence intensity of calibrators decreases with increasing concentration except for curve fits 5 and 6 (assay parameter .14 CRV FIT), where polarization or percent fluorescence intensity increases with concentration. SPLS NOT MONOTONIC.

If the calibration meets the instrument stored calibration criteria, the calibration curve is stored in memory until another calibration curve replaces it. Only the most recent calibration curve is held in memory.

Verifying Calibration Acceptability

Use these three criteria to verify acceptability of a calibration curve:

1. The PERR (polarization error) or ERR (percent error) values must be within the acceptable range indicated in the assay manual insert.
2. The RMSE (root mean squared error) must be within the acceptable range indicated in the assay manual insert.
3. Each level of control must be within the acceptable ranges indicated in the assay manual insert.

If any of these values are out of range, determine the cause and recalibrate, if necessary. (Refer to Section VI under Calibration Fails to Meet Specification.)

When to Recalibrate

Recalibration is required when:

- The memory circuit board (Board #2) is replaced.
- An assay activation (new reagent pool) is issued.

Recalibration may be necessary when:

- Assay control values fall outside of the acceptable range specified in the specific assay section of the assay manual insert.
- PERR, ERR, or RMSE values are out of specification. Refer to Verifying Calibration Acceptability.
- A new lot number of reagent is used.
- A new lot number of buffer is used.
- Any dispense component is replaced.
- Any instrument calibration procedure is performed.
- A wide variation in room temperature is experienced.

To determine whether recalibration is required, each reagent system should be checked by assaying the controls L, M, and H. If the control results are within range, patient results may be run without need for recalibration. If the control results are not within range for a particular assay, refer to Section VI, under Observed Problems. It may be necessary to recalibrate that assay before reporting any patient results.

Introduction

The following paragraphs present the step-by-step procedure for performing a batch assay run.

Before you begin:

- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to Section V, Maintenance.
 - Ensure that a calibration curve has been stored for the assay being performed. To check the calibration date for a specific assay, press **ASSAY XX.22 DISPLY**. The calibration date displays.
 - If running an abused drug assay, ensure the numerical print option desired (T Print, System 6.7) has been selected. Press **SYSTEM 6.7 DISPLY**. If correct, press **STOP**, if not press **EDIT 0** or **1** (as desired) **STORE STOP**.
 - If pretreatment of samples and controls is required, follow the pretreatment procedure as described in the appropriate assay section in the assays manual.
-

Preparing the Carousel

1. Select a numbered assay carousel.
2. Load the carousel with one sample cartridge and cuvette for each sample to be assayed. Ensure that all disposables are clean and free of foreign matter. Some assays require a modified carousel set-up procedure. Refer to the specific assay procedure in the assays manual.) Begin with position one and continue sequentially. Do not skip a position. Ensure all cuvettes are right side up.
3. Lock cuvettes into the carousel by turning the locking mechanism clockwise until it clicks.
4. Pipette the appropriate volume* of patient samples and controls, if needed, into each sample well. Avoid splashing, foaming, or bubbling.
5. Inspect the samples for bubbles and remove any bubbles with applicator sticks (use a different applicator stick for each sample cartridge).

* For most assays 50 μ L sample volume is sufficient; refer to the assays manual for the specific sample volume.

Preparing the Reagent Pack

6. Select the appropriate reagent pack.
 7. Invert gently five times.
 8. Open the reagent pack and check to be sure the vials read **S, T, P**.
NOTE: Some vials read **P, T, P**. 4-pot reagent pack vials read **W, S, T, P**.
 9. Remove the vial caps and place them upside-down in the lid spaces provided.
 10. Inspect the surface of the liquid in the vials for bubbles and remove any bubbles with applicator sticks. (Use a different applicator stick for each vial.)
-

Run Assay

11. Insert the reagent pack into the proper position in the analyzer.
12. Place the loaded assay carousel into the instrument.
13. Close the access door.
14. Press **RUN**.
15. If your instrument is not programmed to record the operator ID, go to step 16. If it is programmed to record this number, the display reads:

OP ID?

Enter your ID number and press **STORE**.

16. If your instrument is not programmed to record the reagent lot number, go to step 17. If it is programmed to record this number, the display reads:

RGT #?

Enter the reagent lot number and press **STORE**.

-
17. If your instrument is not programmed to record the patient ID number, go to step 18. If it is programmed to record this number, the display reads:

ID 1?

Enter the patient ID for carousel position 1 and press **STORE**. This process repeats until a patient ID has been entered for each patient sample (or patient sample replicate group) on the carousel.

18. Verify that the correct assay name is displayed before leaving the analyzer. If the assay name displayed is incorrect, press **STOP** and refer to the Barcode Override procedure in this section.

Clean-Up

19. Wait for an entire printout. The assay is complete when the display reads:

DONE - REMOVE RPAK

20. If the reagent pack is not to be used **immediately**, it should be removed, recapped and placed at proper storage, as described on the labeling.
21. Remove the carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

CAUTION: IF SPLASHING OR FOAMING IS OBSERVED, DO NOT REPORT RESULTS. THESE SYMPTOMS INDICATE A PROBLEM AND REQUIRE CORRECTIVE ACTION. REFER TO SECTION VI, UNDER OBSERVED PROBLEMS.

22. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to Decontamination Procedures in Section I, under Operational Precautions and Limitations.

If separation of glass and plastic is not required, unlock the carousel, invert over a receptacle, and discard the cartridges and cuvettes all at once. Ensure that all sample cartridges and cuvettes have been removed.

If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle, and discard the cuvettes. Ensure that all sample cartridges and cuvettes have been removed.

Reading Therapeutic Drug or Hormone Batch Assay Printouts

The following printout is typical of a therapeutic drug or hormone batch assay. The patient results that are to be reported are found in the column entitled CONC.

| A | DATE: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|---|--------|---------|-------|-------|--|---|----------|--------|--------|--|---|-------|--------|---------|----|---|----------|--------|--------|--|---|-----|--------|--------|--|---|----|-------|--------|--|
| B | TIME: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C | SERIAL #: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D | LOCK = 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| E | OP ID #: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| F | RGT LOT #: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| G | ASSAY: THEOPHYLLINE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| H | CAROUSEL: 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| I | SPL VOL = 2.0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| J | REPS = 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| K | GAIN = 40 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| L | CALIB. DATE: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| M | CALIB. TIME: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| N | CONC = UG/ML | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| O | <table><tr><th>LOC</th><th>CONC</th><th>NET P</th><th>BLK I</th><th></th></tr><tr><td>1</td><td>6.63 LOW</td><td>179.82</td><td>423.57</td><td></td></tr><tr><td>2</td><td>11.73</td><td>155.83</td><td>1971.69</td><td>HI</td></tr><tr><td>3</td><td>25.20 HI</td><td>119.64</td><td>427.91</td><td></td></tr><tr><td>4</td><td>LOW</td><td>220.19</td><td>379.79</td><td></td></tr><tr><td>5</td><td>HI</td><td>82.74</td><td>405.72</td><td></td></tr></table> | LOC | CONC | NET P | BLK I | | 1 | 6.63 LOW | 179.82 | 423.57 | | 2 | 11.73 | 155.83 | 1971.69 | HI | 3 | 25.20 HI | 119.64 | 427.91 | | 4 | LOW | 220.19 | 379.79 | | 5 | HI | 82.74 | 405.72 | |
| LOC | CONC | NET P | BLK I | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | 6.63 LOW | 179.82 | 423.57 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | 11.73 | 155.83 | 1971.69 | HI | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | 25.20 HI | 119.64 | 427.91 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | LOW | 220.19 | 379.79 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | HI | 82.74 | 405.72 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

- A. date of assay run
- B. time of assay run
- C. serial number of instrument
- D. door lock status (0 = off, 1 = on)
- E. operator ID number (optional feature)
- F. reagent lot number (optional feature)
- G. name of assay
- H. assay carousel number
- I. sample volume - final amount of sample in the cuvette in microliters
- J. number of sample replicates
- K. gain
- L. date of last calibration stored
- M. time of last calibration stored
- N. concentration units
- O. location - position in carousel
- P. blank intensity - serum background intensity reading
- Q. net polarization - polarization of sample corrected for background reading
- R. concentration - net polarization converted to concentration units

**Reading Therapeutic Drug
or Hormone Batch
Assay Printouts**

The following paragraphs describe the HI and LOW flags that can appear on the printout. More detailed information is provided in Section VI.

HI and LOW READINGS**HI Printed After BLK I Reading**

- If the blank intensity or background reading exceeds the maximum expected reading (assay parameter .20), HI prints after the blank value.
- If a HI flag appears here, the patient sample may contain another drug or substance that is adding fluorescence.
- If the BLK I value is less than three times the MN TR value, the results are reportable. The MN TR value for a specific assay can be displayed by first pressing **ASSAY PRINT** to obtain a list of available assays. Locate the number corresponding to the name of the assay and press **ASSAY (XX) .21 DISPLY**.
- If the BLK I value is more than three times the MN TR, manually dilute the sample and repeat the run or rerun the sample using dilution protocol.

Refer to the Dilution Protocol procedure in this section.

- If all BLK I readings show HI, it is not an isolated case. Common causes are:

- an open access door
 - contaminated buffer
 - lamp cover off or seated incorrectly
 - contaminated or previously used cuvettes
 - contaminated P reagent vial

HI or LOW Printed After CONC Result




- If any result is outside of the programmed therapeutic range (assay parameters .3 and .4), the patient result is flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.

HI or LOW Printed Instead of CONC Result

- If the Net P value is outside the span of the calibration curve, HI or LOW prints instead of the numeric result.
- If LOW prints, see the Troubleshooting section before proceeding further.
- If LOW is repeated after following all troubleshooting, the concentration may be reported as less than the sensitivity of the specific assay. The sensitivity ranges are provided in the assays manual.
- If HI prints, the test should be rerun using Dilution Protocol. Refer to the Dilution Protocol procedure in this section. If Dilution Protocol is not allowed for the assay, rerun the test following a manual dilution of the sample. Refer to the assays manual for specific instructions for each assay.

Reading Clinical Chemistry Assay Printouts

A printout for a clinical chemistry assay is similar to a therapeutic drug or hormone batch assay printout. Some column headings differ, as shown in the printout below. The patient results that are to be reported are found in the column labeled CONC.

| DATE: | | | |
|---|-----------------|---------|-------------|
| TIME: | | | |
| SERIAL #: | | | |
| LOCK = 1 | | | |
| OP ID #: | | | |
| RGT LOT #: | | | |
| ASSAY: GLUCOSE | | | |
| CAROUSEL: 2 | | | |
| SPL VOL = 3.00 | | | |
| REPS = 1 | | | |
| GAIN = 5 | | | |
| CALIB. DATE: | | | |
| CALIB. TIME: | | | |
| CONC = MG/DL | | | |
| <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>C</p> </div> <div style="text-align: center;">  <p>B</p> </div> <div style="text-align: center;">  <p>A</p> </div> </div> | | | |
| LOC | SAMPLES CONC | PERCENT | FINAL V |
| 1 | 60.25 LOW | 70.90 | 7949.95 |
| 2 | 100.01 | 63.58 | 21224.30 HI |
| 3 | 244.06 HI | 38.67 | 4464.72 |
| 4 | HI | 13.42 | 1455.23 |
| 5 | LOW | 90.54 | 11130.43 |

- A. final vertical intensity reading
- B. percentage of blue and green light not absorbed by the chromogen
- C. final concentration in patient sample

Reading Clinical Chemistry Assay Printouts

The following is an explanation of the HI and LOW flags that are seen on the clinical chemistry printout.

HI AND LOW READINGS**HI or LOW Printed After CONC Result**

- If any result is outside the programmed normal range (assay parameters .3 and .4), the patient result is flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.
-

HI or LOW Printed Instead of CONC Result

- If the percent value is outside the span of the calibration curve, HI or LOW prints instead of a numeric result.
 - If LOW prints, see the Troubleshooting section for corrective action.
 - If HI prints, the test should be rerun using Dilution Protocol. Refer to the Dilution Protocol procedure in this section. If Dilution Protocol is not allowed for the assay, rerun the test following a manual dilution of the sample. Refer to the assays manual for Dilution Protocol availability for each assay.
-

HI Printed After Final V Result

- If the blank intensity reading is greater than the MX BKG (assay parameter .20), HI prints after the Final V value.

Reading Abused Drug Assay Printouts

A printout for an abused drug assay is similar to a therapeutic drug or hormone batch assay printout. The patient results that are to be reported are found in the column labeled CONC. This printout is an example of what prints when System 6.7 (T Print) is set at 0 and the patient ID option is on (1 = on).

| DATE: | | | |
|---------------------------|-----------------|--------|------------|
| TIME: | | | |
| SERIAL #: | | | |
| LOCK = 1 | | | |
| OP ID: | | | |
| RGT LOT # | | | |
| ASSAY: AMPHET/METH U | | | |
| CAROUSEL: 3 | | | |
| SPL VOL = 8.0 | | | |
| REPS = 1 | | | |
| GAIN = 20 | | | |
| CALIB DATE: | | | |
| CALIB TIME: | | | |
| CONC = NG/ML | | | |
| STORED THRESHOLD = 300.00 | | | |
| LOC | SAMPLES CONC | NET P | BLK I |
| B | 1 ID # 12 | | |
| | LOW | 214.71 | 716.34 |
| | 2 ID # 15 | | |
| | > MX BKG | | 1498.43 HI |
| | 3 ID # 34 | | |
| | LOW | 213.85 | 717.72 |
| C | 4 ID # 45 | | |
| | 530.00 >= T | 170.19 | 624.07 |
| | 5 ID # 90 | | |
| | 530.00 >= T | 170.36 | 625.90 |
| | 6 ID # 95 | | |
| | > MX BKG | | 1506.15 HI |

- A. threshold value - same value as assay parameter .4 THRSHLD
- B. patient ID - patient identification
- C. >= T - concentration is greater than or equal to the threshold

Below is an example of the printout when System 6.7 (T Print) is set to 1, and System 6.6 (PAT ID) is set to 0, (0 = off).

| | | |
|---------------------------|-----------------|-------|
| DATE: | | |
| TIME: | | |
| SERIAL #: | | |
| LOCK = 1 | | |
| OP ID: | | |
| RGT LOT #: | | |
| ASSAY: AMPHET/METH U | | |
| CAROUSEL: 3 | | |
| SPL VOL = 8.00 | | |
| REPS = 1 | | |
| GAIN = 20 | | |
| CALIB DATE: | | |
| CALIB TIME: | | |
| CONC = NG/ML | | |
| STORED THRESHOLD = 300.00 | | |
| LOC | SAMPLES CONC | BLK I |
| 1 | NONE DETECTED | |
| 2 | > MX BKG | |
| 3 | NONE DETECTED | |
| 4 | > = THRESHOLD | |
| 5 | > = THRESHOLD | |
| 6 | > MX BKG | |

**Reading Abused Drug
Assay Printouts**

The following paragraphs explain the print options available for an abused drug assay printout using different 6.7 settings.

SYSTEM 6.7 = 0

- If SYSTM 6.7 = 0, then the $\geq T$ (greater than or equal to threshold) prints following the numerical concentration result if that concentration is higher than the stored threshold. If BLK I exceeds assay parameter .20 MX BKG, > MX BKG prints under CONC and HI prints following the BLK I reading.

If a HI flag appears, the patient sample must not be diluted and rerun. Assay parameter .20 (MX BKG) should not be edited to a greater value than is found for that assay in the assays manual.

If LOW prints instead of a CONC result the mP reading for the sample is higher than the mP used in the calibration curve for the A Calibrator. See the Troubleshooting section under Printed Error Codes for more information.

SYSTEM 6.7 = 1

- If SYSTM 6.7 = 1, then \geq THRESHOLD or NONE DETECTED prints under CONC and after the location number. No numerical concentration result is printed. No NET P is printed.

BLK I is not printed except when the background intensity exceeds assay parameter .20 MX BKG. In this case > MX BKG prints under CONC and HI prints following the BLK I reading.

If a HI flag appears, the patient sample must not be diluted and rerun. Assay parameter .20 (MX BKG) should not be edited to a greater value than is found for that assay in the assays manual.

If NONE DETECTED prints instead of a CONC result, the sample value is less than the stored threshold. See the Troubleshooting section under Printed Error Codes for more information.

- With either setting of 6.7, STORED THRESHOLD = prints before the assay results. The stored threshold value, printed, is the same value as assay parameter .4 (THRSHLD).

Introduction

The following paragraphs present the step-by-step procedure for performing a unit dose assay run.

Before you begin:

- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to Section V, Maintenance.
- Ensure that a unit dose calibration curve has been stored for each assay being performed. To check the calibration date for a group of assays or a specific assay, press **SYSTEM 4.3 RUN**, enter **1** and press **STORE**. For [FROM ASSAY # __] enter the first or only assay number and press **STORE**. For [TO ASSAY # __] enter the last or only assay number and press **STORE**. The date and time of the unit dose calibration(s) print.
- If pretreatment of samples and controls is required, follow the pretreatment procedure as described in the appropriate assay section in the assays manual.

Preparing the Carousel

1. Select the unit dose assay carousel.

NOTES: Before attaching the cuvette to the cartridge, visually inspect the foil seals on the reagent wells of the cartridge for signs of leakage (a flaky white powder around the edges of the foil). Do not use any cartridge that appears to have leaked. For more information, contact the Customer Support Center.

Ensure that all disposables are clean and free of foreign matter before use.

2. Beginning with Position 1, insert an appropriate unit dose cartridge, after attaching a cuvette, for each assay being run. Load the cartridges sequentially, being sure not to skip a position in the carousel.
3. Lock the unit dose carousel by turning the locking mechanism clockwise until it clicks.
4. Pipette the appropriate volume* of sample into the sample well of each cartridge. Avoid splashing, foaming, or bubbling.
5. Inspect the samples for bubbles and remove any bubbles with applicator sticks. (Use a different applicator stick for each cartridge.)
6. After all samples have been pipetted, place the carousel into the instrument and close the access door.

NOTE: The Fetal Lung Maturity and Ethosuximide assays cannot be run on the same carousel with other unit dose assays.

* For most assays 50 μ L sample volume is sufficient. Refer to the assays manual for the specific sample volume.

Run Assays

7. Press **RUN**.
8. If your instrument is not programmed to record the operator ID, go to step 9. If it is programmed to record this number, the display reads:

OP ID?

Enter your ID number and press **STORE**.

NOTE: Reagent lot numbers and patient ID numbers cannot be entered in the unit dose mode of operation.

9. The system reads the unit dose assay carousel and displays:

UNIT DOSE SPLS

A unit dose header prints. The system reads the barcode on each of the cartridges and displays the assay name for each assay to be performed. As each cartridge barcode is read, the assay name, its position on the carousel, and the calibration date prints.

After the assay list is printed, verify that each assay name and its position is correct. The system automatically begins testing after 15 seconds. If an assay name is incorrect, press **STOP** and see instructions for Barcode Override - Unit Dose, in this section.

Clean-Up

10. After final readings are taken, assay results for the samples print. The assay is complete when the display reads:

ASSAY COMPLETE

then,

READY

11. Remove the carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

CAUTION: IF SPLASHING OR FOAMING IS OBSERVED, DO NOT REPORT RESULTS. THESE SYMPTOMS INDICATE A PROBLEM AND REQUIRE CORRECTIVE ACTION. REFER TO SECTION VI, TROUBLESHOOTING, UNDER OBSERVED PROBLEMS.

12. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to Decontamination Procedures in the Operational Precautions and Limitations section.

If separation of plastic and glass is not required, unlock the carousel, remove the cartridge, with cuvette attached and discard into a receptacle.

If separation of glass and plastic is required, unlock the carousel and remove the cartridge with cuvette attached. Detach cuvette and discard in glass disposal. Discard the cartridge into its proper receptacle.

Reading Unit Dose Assay Printouts

The following printout is typical of a unit dose assay.

```

A ██████████ SAMPLES
B ██████████ DATE:
C ██████████ TIME:
D ██████████ SERIAL #:
E ██████████ LOCK = 1
F ██████████ OP ID #:

G ██████████
    ASSAY KEY
    LOC 1  ACETAMINOPHEN      CDATE:
    LOC 2  ACETAMINOPHEN      CDATE:
    LOC 3  PROCAINAMIDE        CDATE:
    LOC 4  PROCAINAMIDE        CDATE:
    LOC 5  NAPA                CDATE:
    LOC 6  NAPA                CDATE:

J ██████████
L ██████████
    1  ACETAMINOPHEN      9.52 ■ LO ■ UG/ML
    NET P: 223.04  BLK I: 326.84

    2  ACETAMINOPHEN      20.21 ■ HI ■ UG/ML
    NET P: 206.63  BLK I: 425.00

    3  PROCAINAMIDE        9.01      UG/ML

    4  PROCAINAMIDE        ■ LO ■ UG/ML
    NET P: 228.50  BLK I: 410.80

    5  NAPA                9.36      UG/ML

    6  NAPA                ■ HI ■ UG/ML
    NET P: 131.66  BLK I: 415.87

```

- A. unit dose header
- B. date of assay
- C. time of assay
- D. serial number of instrument
- E. door lock (0 = off, 1 = on)
- F. operator ID number (optional feature)
- G. location - position in carousel
- H. name of assay
- I. date of last calibration stored
- J. assay name for the corresponding location
- K. concentration - net polarization converted to concentration units
- L. net polarization - polarization of sample corrected for background reading (only printed when a HI or LO flag occurs)
- M. blank intensity - serum background intensity (only printed when a HI or LO flag occurs)

**Reading Unit Dose
Assay Printouts**

The following is a description of the HI and LO flags that can appear on the printout. Note that NET P and BLK I values are only printed when a flag occurs. More detailed information concerning these flags can be found in Section VI, Troubleshooting.

HI AND LOW READINGS

HI or LOW Printed After CONC Result

- If any result is outside of the programmed therapeutic range (assay parameters .3 and .4), the patient will be flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.
-

HI or LOW Printed Instead of CONC Result

- If the Net P value is outside the span of the calibration curve, HI or LOW prints instead of the numeric result.
- If LOW prints, the concentration may be reported as less than the sensitivity of the specific assay. The sensitivity ranges are found in the assays manual under the specific assay heading.

If HI prints, the test should be rerun following a manual dilution of the sample. Refer to the assays manual for assay specific instructions.

Dilution Protocol Procedure

The Dilution Protocol procedure can be used to analyze a sample result when the concentration of that sample prints HI instead of a numerical result.

NOTE: This procedure is only available for some assays. Refer to the specific assay manual insert for Dilution Protocol availability.

1. Introduce sample into a sample cartridge in the assay carousel.
2. Refer to the assay list printout. If one is not available, press **ASSAY PRINT**. Note the assay number for the assay you are performing.
3. Press **ASSAY XX.1 EDIT**. Divide the SPL VOL displayed by the desired dilution ratio; it is suggested to begin with two.
4. Enter the numerical value of the desired sample volume (i.e., 1 divided by 2 = .5; enter .5) and then **STORE STOP**.
5. Press **RUN**. At the completion of the run, the polarization and calculated concentration which the analyzer multiplies by the dilution ratio, prints.

NOTES: If RST SPL (System 2.3) is set to 1, the sample volume is automatically set by the analyzer to the value of the calibration volume at the completion of the Dilution Protocol. This feature is not operable with HDL Cholesterol, CRP or unit dose assays.

Specific proteins are run in the unit dose mode. However, RST SPL is enabled for these assays.

Otherwise, the sample volume must be manually returned to its original value by the operator as follows:

1. Press **ASSAY XX.1 EDIT**.
2. Enter the original sample volume and press **STORE STOP**. The instrument returns to operational status.

Barcode Override

Barcode override procedures may be used if the barcode label is misread. This procedure is provided only to help you continue the run but should not be used routinely. If a barcode problem arises, finish the run and then refer to Section VI, for assistance.

Batch

If an incorrect assay name is displayed after **RUN** is pressed:

1. Press **STOP**. The display returns to [READY].
2. Verify that the correct reagent pack was loaded.
3. Refer to the assay list printout. If not available, press **ASSAY PRINT**. Select from this list the appropriate assay.
4. Press **ASSAY**, enter the assay number, and press **RUN**. The display reads:

CALIBRATION?

5. If performing a calibration run, press **STORE**. (This activates the calibration procedure.)
6. If performing an assay, press **NEXT**. The display reads:

CAROUSEL #?

7. Enter the carousel number and press **STORE**. This activates the assay run. Results print upon completion.

NOTE: This procedure is modified for assays utilizing interactive dilution protocol. Refer to the Interactive Dilution Protocol section of the appropriate assays manual insert.

Unit Dose

There are three types of override procedures for unit dose testing. These are:

1. When an individual cartridge is misread and the error code [ERR-STOP-FIX-GO] displays during an assay or calibration run.
2. When the barcode reader is not working properly during an assay run.
3. When the barcode reader is not working properly during calibration.

NOTE: Do not open door when performing barcode override as it will trigger the door alarm and abort the barcode override. Refer to the header printout for the barcode fail message of the position in error.

A description of these three procedures follows:

1. Error Code Displayed – Assay Run

NOTE: The system allows 15 seconds to begin to correct this error. If step 1 is not started within 15 seconds, the system continues to the next position and the position causing the error is not assayed.

To override the barcode reader when the message [ERR-STOP-FIX-GO] appears during an assay run:

- a. Press **NEXT**. The display reads:

LOC 1 ASSAY #__ __

- b. Check the printout to determine which cartridge is causing the error. BARCODE FAIL prints in the position where the assay name should print.
- c. Press **NEXT** to move to the carousel location that needs to be corrected.
- d. Enter the correct assay number and press **STORE**.
- e. If the error has occurred on subsequent positions, repeat steps c and d.
- f. When all correct assay numbers are entered, press **RUN**. A correct list of assays prints for verification.
- g. When [ASSAY LIST OK?] appears in the display, verify the list is correct and press **STORE** to start the assay run. If the list is not correct, repeat the procedure beginning with step a.

NOTE: If the **STORE** key is not pressed after verifying the assay list is correct, the assay run does not start. The message [ASSAY LIST OK?] will remain in the display.

2. Error Code Displayed - Calibration Run

When any cartridge after the position 1 cartridge is misread by the barcode reader:

- a. The display reads:

ERR-STOP OR FIX

- b. To continue the run, press **NEXT**. The display reads:

ASSAY #__ __

- c. Enter the correct assay number and press **RUN**. Calibration will begin.
-

3. Barcode Failure - Assay Run

When the barcode reader misreads the cartridges during an assay run:

- a. Press **ASSAY . RUN**. The display reads:

CALIBRATION?

- b. Press **NEXT**. The display reads:

ENTER ASSAY?

- c. Press **STORE**. The display reads:

LOC 1 ASSAY #__ __

- d. Enter the assay number for the cartridge in location 1 and press **STORE**. The display reads:

LOC 2 ASSAY #__ __

- e. Repeat step d for **each** position containing a unit dose cartridge. When all assay numbers are entered, press **RUN**.
- f. When [ASSAY LIST OK?] appears in the display, verify the list is correct and press **STORE**.

NOTE: In this case of barcode reading failure, the override procedure must be performed on each position containing a cartridge.

4. Barcode Failure - Calibration Run

When the barcode reader is not reading properly during calibration:

- a. Press **ASSAY . RUN**. The display reads:

CALIBRATION?

- b. Press **STORE**. The display reads:

ASSAY #__ __

- c. Enter the number of the assay to be calibrated and press **RUN**. Calibration is performed automatically for the assay number entered.

NOTE: During unit dose barcode override, editing can only proceed forward, not backward. Also, once you enter a position, it cannot be cleared without pressing **STOP** and repeating the barcode override procedure.

Centrifuge Controls

NOTE: For the X SYSTEMS™ Centrifuge, refer to the X SYSTEMS Centrifuge Instruction Guide.

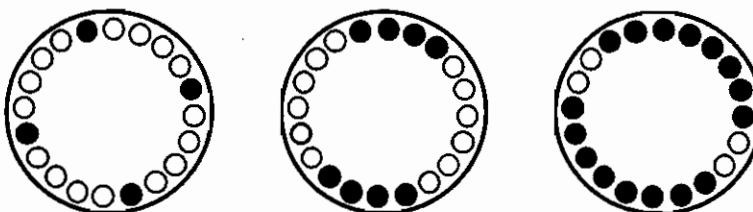
The TD_x Centrifuge has one time-control dial and one indicator lamp on the front panel. The time-control dial is continuously adjusted for setting run times from 0 to 5 minutes in increments of 15 seconds. This control must be reset to make successive runs of the same duration.

The indicator lamp is a green lamp providing a visual alert that power is applied to the motor circuit (i.e., an operating period has been selected on the time-control dial). The lid cannot be opened as long as unexpired operating time remains set on the time control.

A screwdriver-adjustable, continuously variable potentiometer is accessed through an opening in the side panel whenever recalibration is required.

Loading the Head

1. The head should be loaded only with an **even number** of the same capacity tubes containing samples of the same weight.
2. If less than a full load is to be centrifuged, identical samples should be loaded 180 degrees apart.
3. If an uneven number of samples is to be centrifuged, fill an empty tube with water to the same level as the sample and use as a balance tube.
4. Make sure that the caps are snapped on the tubes.



Initiating the Run

1. Close the lid.
 2. Set the time-control dial to the desired centrifugation interval.
 3. After the set time expires (the indicator lamp goes off), allow the head to come to a complete stop.
 4. Open the lid and remove sample tubes.
-

Run Interruption

1. Excessive noise and/or vibration during operation indicates an out-of-balance load or an improperly seated head.
2. If an unusual noise is heard during a run, turn the time control to zero immediately to discontinue power.
3. Wait until the head comes to a complete stop.
4. Inspect the head for tube balance and adjust if necessary.
5. Ensure that the head is correctly mounted on the drive shaft.

.

Introduction

This section provides a description of system checks, diagnostic tests, and additional system verifications that can be performed on the TD_x® System.

SYSTEM CHECKS

- System 1 - SYSTEM STATUS

Provides current status of the instrument: date, time, temperature of the three heating systems (liquid/optics/air), and current software version.

- System 2 - SYSTEM CONTROL

Directs function of: beep, lock, reset sample volume, baud, polarization bias, thermal offset, airset, and paper.

- System 3 - SYSTEM PARAMS (system parameters)

Defines positions of the stepper motors for the batch mode of operation.

- System 4 - RECALL DATA

Reprints or displays information from the most recent run and recalls calibration dates for all assays.

- System 5 - ASSAY UPDATES - (assay activation)

Activates parameters for new assays and for changes in reagent antibody pools.

- System 6 - IDENTIFICATION

Assigns identifying information to the printout and lists assays by category.

- System 7 - THYROID FEATURES

- System 8 - UNIT DOSE PARAMS (unit dose parameters)

Defines positions of the stepper motor and timing for the unit dose mode of operation.

- System 9 - SHARED PACK OPTS - (shared pack options)

Allows sharing of reagent packs for assays that are offered as both a total and a free assay.

DIAGNOSTIC TESTS

- Test 1 - MAINTENANCE

- Test 2 - SPEC CHECKS (specification checks)

Tests instrument subsystems independent of the chemistries.

2.1 Temperature Check*

2.2 Photo Check*

2.3 Pipet Check*

- Test 3 - CALIBRATION

Calibrates several subsystems of the analyzer.

3.1 Temperature Calibration

3.2 Boom Calibration

3.3 Carousel Calibration

3.4 Photo Calibration

3.5 Z-Boom Calibration

3.6 Unit Dose Boom Calibration

3.7 4-Pot Reagent Pack Boom Calibration

3.8 Turbo Carousel Calibration**

- Test 4 - HAND CONTROL

Controls the mechanical operation of all stepper motors and monitors the status of systems.

- Test 5 - BOARD TESTS

Tests board integrity (most are used only by the factory or service).

- Test 6 - SPECIAL TESTS

Tests are used only by the factory or service with the exception of the two tests listed below.

6.3 Dispense Check

6.4 Turbo Correction Factory Entry**

ADDITIONAL SYSTEM VERIFICATIONS

- Buffer Run (observation of dispense process)
- Coefficient of Variation (CV) Check
- Background Subtraction Check
- Carryover Check (probe performance)

* Refer to Section V for the test procedure.

** Refer to the TDxFLx® & TDx Turbo® Operation Supplement for the test procedure.

**System Checks
(System Monitor)**

Nine system checks are available on the TD_x System. To obtain a listing of the checks, press **SYSTEM PRINT**.

System 1 - SYSTEM STATUS
 System 2 - SYSTEM CONTROL
 System 3 - SYSTEM PARAMS
 System 4 - RECALL DATA
 System 5 - ASSAY UPDATES
 System 6 - IDENTIFICATION
 System 7 - THYROID FEATURES
 System 8 - UNIT DOSE PARAMS
 System 9 - SHARED PACK OPTS

A description of these systems follows.

NOTE: Refer to Keypad Functions under Section I, System Description, for details on how to display, print, or edit the parameters of the system checks.

**System 1 -
System Status**

This system provides a printout or display of the current status of the following:

- | | | |
|-------|-------|--|
| 1.1 | DATE | Date currently in memory. |
| <hr/> | | |
| 1.2 | TIME | Time currently in memory. |
| <hr/> | | |
| 1.3 | LIQ C | Current temperature of the liquid heater (35.0 ± 0.5°C). |
| <hr/> | | |
| 1.4 | PHO C | Current temperature of the optics assembly (40.2 ± 0.5°C). |
| <hr/> | | |
| 1.5 | AIR C | Current temperature of the air heater (30°C to 37°C, within ± 2°C of AIRSET System 2.7). |
| <hr/> | | |
| 1.6 | REV | Current software version. |
| <hr/> | | |

NOTE: Only System 1.1 and 1.2 can be edited, all other information is status only.

**System 2 -
System Control**

The System Control directs several functions of the TD_x System. Some of the items are automatically set by the TD_x System during special calibration procedures.

2.1 BEEP Controls beeper (0 = off, 1 = on).

2.2 LOCK Controls door lock sensor (0 = off, 1 = on).

2.3 RST SPL Controls automatic resetting of the sample volume following a Dilution Protocol assay. If the function is on, SPL VOL is automatically reset to the value of CAL VOL (0 = off, 1 = on). This feature is active for all assays except HDL Cholesterol, C-Reactive Protein, and unit dose assays.

2.4 BAUD Controls the baud rate for sending printed results to a peripheral device, if available in the software. Available baud rates are 110, 300, 600, 1200, 2400 and 4800.

2.5 P BIAS Polarization Bias (P BIAS) is a normalization factor for the PMT to correct for the placement of the polarizer/liquid crystal portion of the optics. System 2.5 is automatically set by the TD_x System during Photo Calibration (Test 3.4).

2.6 THM OFF Thermal offset is a parameter used to calibrate the cuvette temperature sensing device. System 2.6 is automatically set by the TD_x System during Temperature Calibration (Test 3.1). (Do not edit except when instructed by the Customer Support Center.)

2.7 AIRSET Airset determines the approximate temperature the TD_x System maintains at READY.

CAUTION: DO NOT EDIT EXCEPT WHEN INSTRUCTED TO DO SO BY THE CUSTOMER SUPPORT CENTER.

2.8 PAPER This control overrides the paper-out switch in the TD_x System for the following tests:

- 2.2 - Photo Check
- 3.1 - Temperature Calibration
- 3.4 - Photo Calibration

**System 3 -
System Parameters**

These system parameters define the positions of the stepper motors that move the carousel and boom arm. Refer to System 8 for unit dose parameters.

3.1 CAR HM Home position for the carousel.

CAUTION: DO NOT EDIT THIS PARAMETER UNLESS INSTRUCTED TO DO SO BY THE CUSTOMER SUPPORT CENTER.

3.2 RBM HM Home position for horizontal (R) boom movement.

3.3 SERM PT R-boom step number when the probe is centered over the sample well.

3.4 PREDIL R-boom step number when the probe is centered over the predilution well.

3.5 CUVETTE R-boom step number when the probe is centered over the cuvette.

3.6 POP PT R-boom step number when the probe is centered over the "P" vial of a 3-pot reagent pack.

3.7 TRA PT R-boom step number when the probe is centered over the "T" vial of a 3-pot reagent pack.

3.8 ANTI PT R-boom step number when the probe is centered over the "S" vial of a 3-pot reagent pack.

3.9 WASTE R-boom step number when the probe is centered over the waste opening.

3.10 STD BAR R-boom step number when the barcode reader is within four to nine steps of detecting the beginning of the reagent pack barcode label.

3.11 REAG BR Same as 3.10.

3.12 CAR RBR R-boom step number when the barcode reader is over the carousel label.

3.13 CAR CBR Carousel step number when the barcode reader is within four to nine steps of detecting the beginning of the carousel barcode label.

-
- | | |
|-------------|--|
| 3.14 ZBM HM | Vertical Z-boom step number when the Z-boom is home. |
|-------------|--|
-
- | | |
|--------------|--|
| 3.15 4POP PT | R-boom step number when the probe is centered over the "P" vial of a 4-pot reagent pack. |
|--------------|--|
-
- | | |
|--------------|--|
| 3.16 4TRA PT | R-boom step number when the probe is centered over the "T" vial of a 4-pot reagent pack. |
|--------------|--|
-
- | | |
|--------------|--|
| 3.17 4ANT PT | R-boom step number when the probe is centered over the "S" vial of a 4-pot reagent pack. |
|--------------|--|
-
- | | |
|--------------|--|
| 3.18 4WSH PT | R-boom step number when the probe is centered over the "W" vial of a 4-pot reagent pack. |
|--------------|--|
-
- | | |
|--------------|--|
| 3.19 RGT BOT | Z-boom step number when the probe reaches near the bottom of the batch reagent vial. A password must be entered before the edited value is accepted. |
|--------------|--|
-

NOTES: An **increase** in R-boom System 3 parameters moves the boom arm to the right. An **increase** in System 3.13 moves the carousel counterclockwise.

A **decrease** in the current R-boom System 3 parameters moves the boom arm to the left. A **decrease** in System 3.13 moves the carousel clockwise.

To reposition the probe horizontally, edit the appropriate parameter (System 3.3-3.9; 3.15-3.18).

To reposition the barcode reader, edit the appropriate parameter (System 3.10-3.12). Refer to the Barcode Reader Lateral Adjustment Check in Section V, Maintenance.

System 4 - Recall Data

This system allows the operator to reprint or display data from the most recently run assay or calibration for the batch or unit dose mode of operation.

CAUTION: DO NOT INITIATE ANOTHER RUN OF ANY TYPE (ASSAY, CALIBRATION, OR DIAGNOSTIC TEST) AFTER THE ASSAY OR CALIBRATION RUN IS COMPLETE, IF SYSTEM 4.1 OR 4.2 OPTIONS ARE TO BE USED.

ONLY SYSTEM PARAMETER 6.7 (T PRINT) MAY BE EDITED PRIOR TO REPRINTING OR DISPLAYING INFORMATION AFTER THE ORIGINAL RUN IS COMPLETE.

4.1 REPRINT DATA. To reprint data for assay or calibration run:

1. Press **SYSTEM 4.1 RUN**. The date and time update to **REPRINT DATE** and **REPRINT TIME**, respectively. Then a line indicating **REPRINTED DATA** prints. The remainder of the information prints exactly as the original. If there is no data to print, the display shows [NO DATA AVAIL].

If it is a unit dose run, a unit dose header prints before **REPRINT DATE**.

4.2 DISPLAY DATA. To display data for an assay run:

1. Press **SYSTEM 4.2 RUN**. The assay name displays.
2. Press **NEXT**. The specific carousel position and concentration value display. If applicable, the specified concentration flags **HI** or **LOW**.
3. Press **NEXT**. The specific carousel position and blank intensity value display. The specific blank intensity flags **HI** if applicable.
4. Repeat steps 2 and 3 until all results are displayed for each carousel position.
 - If a sample was not pipetted, the appropriate error code displays.
 - After the last result displays, the display reads:

ASSAY COMPLETE

then,

READY

To display data for a calibration run:

1. Press **SYSTEM 4.2 RUN**. The assay name displays.
2. Press **NEXT**. The specific carousel position and net polarization value displays as:

P =

3. Press **NEXT**. The specific carousel position and net intensity value display as:

N =

4. Press **NEXT**. The specific carousel position and blank intensity value display as:

B =

5. Repeat steps 2-4 until all raw data is displayed on each carousel position. If the criteria for acceptability are not met, an appropriate error message displays. Refer to Section VI, Troubleshooting, for corrective action.
6. If all data is acceptable, the PERR or ERR for each calibrator displays with the calibrator letter each time **NEXT** is pressed.
 - When all PERR or ERR values have been displayed, the RMSE displays.
 - If a sample is not pipetted, only the carousel position displays.
 - After the RMSE value displays, the display reads:

ASSAY COMPLETE

then,

READY

NOTES: No patient samples or controls display on a calibration run.

Patient ID's, if they have been entered, do not display on an assay run.

When displaying calibration data from an REA assay, only the initial intensities (column labeled **Initial V**) display. The final intensities (column labeled **Final V**) do not display.

4.3 RECALL CAL DATES. To recall calibration date and time for a specific assay or group of assays:

1. Press **SYSTM 4.3 RUN**. [0 = BATCH 1 = U.D.] displays.
2. Press **0** or **1** and **STORE**.
3. The display shows [FROM ASSAY # ____]. If recalling calibration dates for a group of assays, enter the first two-digit assay number and press **STORE**. If recalling only one assay, enter the appropriate assay number and press **STORE**.
4. The display shows [TO ASSAY # ____]. If recalling calibration dates for a group of assays, enter the last two-digit assay number and press **STORE**. If recalling for one assay, reenter the same number as in step 3 (e.g., FROM 01 to 10 or FROM 30 TO 30) and press **STORE**.
5. The calibration date(s) and time(s) print.

**System 5 -
Assay Updates**

This system allows the operator to activate parameters for new assays and for changes in reagent antibody pools.

5.1 ACTIVATE ASSAY. To activate an assay requiring one activation code:

1. Press **SYSTM 5.1 RUN**. [ASSAY NUMBER ____] displays.
2. Enter the appropriate two-digit assay number (e.g., enter assay number 7 as 07).
3. Press **STORE**. The display shows [#=] followed by 14 blanks.
4. Enter the 14-digit activation code obtained from the kit enclosure or through the Customer Support Center. If an error is made during entry of the code, press **CLEAR** to erase the last digit entered.
5. When the code is entered correctly, press **STORE**. [ASSAY ACTIVATED] and then [READY] displays.
6. Press **ASSAY XX PRINT** (using the appropriate two-digit assay number) to obtain a printout of the assay parameters after activation. Verify that these agree with the parameters given in the kit enclosure or through the Customer Support Center. Edit any parameters to the correct values if necessary.
7. Calibrate the newly activated assay prior to an assay run.

5.2 Q.C. PARAMETERS. To activate an assay with multiple activation codes:

1. Follow steps 1-5 of the activation procedure requiring one activation code (System 5.1).
2. Press **SYSTM 5.2 RUN**. [0=BATCH 1=U.D.____] displays.
3. Press **0** to activate a batch assay; press **1** to activate a unit dose assay. Then press **STORE**. [ASSAY NUMBER] displays.
4. Enter the appropriate two-digit assay number.
5. Press **STORE**. The display shows [#1=] followed by 13 blanks.
6. Enter the first 13-digit activation code obtained from the kit enclosure or through the Customer Support Center.
NOTE: If an error is made during entry of a code, press **CLEAR** to erase the code and reenter all 13 digits.
7. When the code is entered correctly, press **STORE**. The display shows [#2=] followed by 13 blanks.
8. Enter the second 13-digit activation code obtained from the kit enclosure or through the Customer Support Center.
9. When the code is entered correctly, press **STORE**. The display shows [#3=] followed by 13 blanks.
10. Enter the third 13-digit activation code obtained from the kit enclosure or through the Customer Support Center.

11. When the code is entered correctly, press **STORE**. [ASSAY ACTIVATED] and then [READY] displays.
12. Press **ASSAY XX PRINT** (using the appropriate two-digit assay number) to obtain a printout of the assay parameters after activation. Verify that these agree with the parameters given in the kit enclosure or through the Customer Support Center. Edit parameters to the correct values as necessary.
13. Calibrate the newly activated assay prior to running an assay run.

System 6 - Identification

This system allows the operator to place identifying information on the printout, or to request categorical information about the assays that are available or under development.

- | | | |
|-------|------------------|---|
| 6.1 | SERIAL# | The five-digit serial number of your TD _x analyzer is stored at factory set. Any attempt to edit this parameter results in the message [WRT PROTECT] to be displayed. |
| <hr/> | | |
| 6.2 | ASSAY CATEGORIES | This allows the operator to obtain a list, by assay categories, of all assays currently available and under development. To obtain this list, press SYSTEM 6.2 RUN . |
| <hr/> | | |
| 6.3 | OP ID # | <p>This feature allows the operator to enter an operator ID (up to nine digits). If this feature is on (1 = on), after pressing RUN, the display reads [OP ID?]. Enter the appropriate number and press STORE. If an error is made during the number entry, press CLEAR prior to pressing STORE. When the correct number has been entered, press STORE. This information appears on the assay header.</p> <p>If this feature is off (0 = off), no prompt for OP ID appears on the display, and this information does not appear on the printout.</p> |
| <hr/> | | |
| 6.4 | PBR # | Not active |

-
- 6.5 RGT LOT** This feature allows the operator to enter a reagent lot number (up to nine digits) for batch assays and calibration runs. This feature is not activated for unit dose or Turbo[®] Specific Proteins assays. If this feature is on (1=on), after pressing **RUN**, the display reads [RGT #?]. Enter the appropriate number and press **STORE**. If an error is made during entry of the number, press **CLEAR** prior to pressing **STORE**. When the correct number is entered, press **STORE**. This information appears on the assay header.

If this feature is off (0=off), no prompt for reagent lot number appears on the display, and this information does not appear on the printout.

-
- 6.6 PAT ID** This feature allows the operator to enter a patient ID (up to ten digits) for each patient sample on a batch or Turbo assay carousel. This feature is only activated for Turbo unit dose assays. If this feature is on (1=on), after pressing **RUN**, the display reads [ID XX?], XX is the carousel position starting with #1. Enter the appropriate number and press **STORE**. If an error is made during entry of the number, press **CLEAR** prior to pressing **STORE**. When the correct number is entered press **STORE**. A number must be entered for each different patient group (or replicate) on the assay carousel. (Example: If sample replicates are set at 2, the display prompts for ID numbers in locations 1, 3, 5, 7, 9, etc. When the final patient ID is entered, press **STORE**.) This information appears on the assay printout, just above the patient results.

If this feature is off (0=off), no prompt for patient ID appears on the display, and this information does not appear on the printout.

-
- 6.7 T PRINT** This feature is only operable for abused drug assays and controls how the results print for an assay run.

If **T PRINT** is 1, no numerical values print for the patient results, only **NONE DETECTED** or **>= THRESHOLD**.

If **T PRINT** is 0, numerical results print along with **LOW** or **>= T** next to the result.

6.8 TOT T3 Not active.

**System 7 -
Thyroid Feature**

Refer to the T-Uptake assay insert in the assays manual for complete instructions regarding this feature.

**System 8 -
Unit Dose Parameters**

This system defines additional positions and actions for the carousel and boom arm stepper motors when the TD_x[®] System is functioning in the unit dose mode. These parameters, in conjunction with the applicable System 3 parameters, direct the positions of the boom arm and carousel during specific steps of a unit dose assay or calibration run.

8.1 UD RBM R-boom step number when the barcode reader is over the unit dose cartridge barcode label.

8.2 UD CAR Carousel shift (from tab*) to position the barcode reader within seven steps of detecting the transition from white to black of the unit dose cartridge barcode label.

8.3 UD POP R-boom step number when the probe is centered over the "P" well on the unit dose cartridge.

8.4 UD TRA R-boom step number when the probe is centered over the "T" well on the unit dose cartridge.

8.5 UD ANTI R-boom step number when the probe is centered over the "S" well on the unit dose cartridge.

8.6 UD SH A Carousel shift (from tab*) to position the probe over the center of the "S" well on the unit dose cartridge.

8.7 UD SH P Carousel shift (from tab*) to position the probe over the center of the "P" well on the unit dose cartridge.

8.8 UD PUNC The number of steps the Z-boom will move down after first sensing foil on initial puncture. After moving down the number of steps specified in System 8.8, the Z-boom will stop and pause for the period of time specified by System 8.9.

* Tab = One of 21 positions (20 cartridge positions + 1 carousel barcode label position)

8.9 UD WAIT The length of time for the pause in Z-boom motion after the initial puncture of foil and drop of the number of steps specified in System 8.8. This time is expressed as the number of 1/600 seconds. If System 8.9 = 300, then the pause will be 300/600 or ½ second. After the pause, the Z-boom moves down to allow the probe to find and pipette reagent.

8.10 UD R B Liquid-level low trip point for the unit dose cartridge reagent wells. If the Z-boom has to drop this far to find reagent, there is too little reagent to perform the assay. A "LIQUID LEVEL LO" message prints in place of results for this position on the carousel.

System Parameters 8.1 through 8.5 are automatically set during Unit Dose Boom Calibration (Test 3.6). They can also be determined manually by use of the hand control capabilities of the TD_x® System and then edited in using the keyboard. These parameters are specific to a given instrument.

System Parameters 8.6 through 8.10 are the same for all instruments.

CAUTION: DO NOT EDIT THESE PARAMETERS UNLESS SO DIRECTED BY THE CUSTOMER SUPPORT CENTER.

System 9 - Shared Pack Options

This system allows optional sharing of reagent packs for the following pairs of assays:

| | |
|--------------------|-------------------------|
| 44 - Total Estriol | 66 - Free Estriol |
| 04 - Phenytoin | 26 - Free Phenytoin |
| 09 - Carbamazepine | 32 - Free Carbamazepine |
| 08 - Valproic Acid | 17 - Free Valproic Acid |

9.1 ESTRL 0 = off, 1 = on

9.2 PHEN 0 = off, 1 = on

9.3 CARB 0 = off, 1 = on

9.4 VALPR 0 = off, 1 = on

When this option is set to "on" (1) for the Estriol (or any of the) assay pairs, and the assay run is initiated, the TD_x display reads:

TOTAL ESTRIOL?

If **STORE** is entered, Total Estriol assay is run. If **NEXT** is entered, the display reads:

FREE ESTRIOL?

When **STORE** is entered, Free Estriol is run.

All paired assays may be run in this manner. This option eliminates the need for barcode override when running the free assays.

Diagnostic Tests

The TD_x® System is self-diagnostic for many major components. To obtain a listing of the various types of diagnostic tests in the instrument, press **TEST PRINT**. A list of the following diagnostic tests prints:

Test 1 - MAINTENANCE

Test 2 - SPEC CHECKS

Test 3 - CALIBRATION

Test 4 - HAND CONTROL

Test 5 - BOARD TESTS

Test 6 - SPECIAL TESTS

A description of these tests follows.

NOTE: Refer to Keypad Functions under Section I, System Description, for details on how to display, print, or edit the parameters of the diagnostic tests.

Test 1 - Maintenance

All maintenance diagnostic tests are used by the manufacturer to verify system operation and should not be used by the operator.

**Test 2 -
Specification Checks**

Specification Checks test instrument subsystems independent of the chemistries. They are performed to verify instrument operation during installation and as part of the routine maintenance program for the instrument. To obtain a listing of the specification checks, press **TEST 2 PRINT**. The following options print:

Test 2.1 - TEMP CHECK

Test 2.2 - PHOTO CHECK

2.2.1 - GAIN

Test 2.3 - PIPE CHECK

**Test 2.1 -
Temperature Check**

This test checks the operation of all temperature control circuitry. It does so by measuring the temperatures of the three heating systems (air, optics, and liquid) during various test operations.

This test is performed upon installation and routinely as a monthly maintenance procedure. Directions for performing the Temperature Check procedure are found in Section V, Maintenance.

Test 2.2 - Photo Check

The Photo Check diagnostic test is a check of the optical system specifications. The procedure helps to ensure photometer/optical system reproducibility.

This test is performed upon installation and routinely as a weekly maintenance procedure. Directions for performing the Photo Check procedure can be found in Section V, Maintenance.

Test 2.3 - Pipet Check

This test is used to check the system's ability to perform linear pipetting, independent of the chemistries.

This test is performed upon installation and as a monthly maintenance procedure. Directions for performing the Pipet Check procedure can be found in Section V, Maintenance.

Test 3 - Calibration

These tests provide automatic calibration of several subsystems of the TD_x System. Several calibration tests are available for the TD_x System. To obtain a listing of these tests, press **TEST 3 PRINT**. The following options print:

Test 3.1 - TEMP CAL

Test 3.2 - BOOM CAL

3.2.1 - RPK ST

3.2.2 - RPK P

3.2.3 - PRD CUP

3.2.4 - PRD SRM

3.2.5 - CAR STR

3.2.6 - CAR STC

Test 3.3 - CRSL CAL

Test 3.4 - PHOTO CAL

3.4.1 - GAIN

3.4.2 - INTENS

3.4.3 - HV COEF

3.4.4 - POL

Test 3.5 - ZBOOM CAL

Test 3.6 - U.D. BOOM CAL

Test 3.7 - 4 POT BOOM CAL

Test 3.8 - TURBO CRSL CAL

**Test 3.1 -
Temperature Calibration**

The purpose of this procedure is to recalibrate System 2.6 (THM OFF) when the cuvette temperature with liquid is out of specification during TEMP CHECK (Test 2.1).

NOTES: This procedure should not be performed unless instructed by the Customer Support Center.

This procedure requires the use of an external temperature probe. A suitable device, List No. 9520-37, is available through Abbott Laboratories. The temperature monitor and probe used must be accurate to $\pm 0.1^{\circ}\text{C}$.

1. Insert empty cuvettes into positions 9, 10 and 11 of a carousel. Lock the cuvettes into position.
2. Place the carousel into the instrument. Leave the door open.
3. Press **TEST 3.1 RUN**. The display reads [TEMP CAL]. Two milliliters of buffer is dispensed into the three cuvettes.
4. Warm the external temperature probe to approximately 34°C (hold it tightly in your hand).
5. When the display changes to [INSERT PROBE], insert the prewarmed temperature probe into the cuvette in position 10.
6. Press **STORE**. The display reads [TEMP SETTLE]. This message remains for several seconds while the temperature probe is equilibrating.
7. When the display changes to [ENTER DEG C ____ . ____] and the temperature on the monitor is within range, enter the reading of the temperature probe to the nearest tenth of a degree.

The temperature on the monitor should read between 33.5°C – 34.5°C . (If an incorrect entry is made press **CLEAR**, and enter the correct temperature. When the temperature has been entered correctly, press **STORE**. Remove the temperature probe from the cuvette immediately. If the temperature is out of range, press **STOP** and contact the Customer Support Center for additional instructions. Assays can continue to be run while waiting to correct a temperature problem if QC is within specifications.)

System 2.6 THM OFF is calculated and stored into memory.

The display flashes [CALIB COMPLETE] and then [READY].

**Test 3.2 -
Boom Calibration**

This diagnostic test determines and stores in memory the correct positions for the movement of the boom and carousel (Systems 3.3 - 3.14). This procedure, as follows, is for the batch mode of operation. Refer to Test 3.6 for the Unit Dose Boom Calibration.

1. Select a calibration carousel.
2. Place sample cartridges in positions 1, 5, 10, 15 and 20. Place a cuvette in position 1. Lock the cuvette into position.
3. Accurately pipette 50 μ L of X SYSTEMS™ Dilution Buffer into the sample well of each sample cartridge. Pipette the fluid volume directly into the bottom of the sample wells.
4. Place the carousel into the instrument. Leave the access door open.
5. Remove the vial caps from a 3-pot reagent pack and place the pack into the instrument.
6. Press **TEST 3.2 RUN**. The display reads [BOOM CAL].

The boom and carousel perform these movements:

- a. Boom seeks home.
 - b. Carousel rotates.
 - c. Barcode reader locates the reagent pack barcode (Systems 3.10 and 3.11).
 - d. Carousel rotates.
 - e. Barcode reader finds the edge of the carousel label holder (System 3.12).
 - f. Carousel rotates.
 - g. Barcode reader locates carousel barcode (System 3.13).
 - h. Carousel rotates.
 - i. Boom moves home.
7. After the instrument has determined the correct barcode positions, the probe moves to each of the following positions allowing the operator to adjust the probe to the center:
 - a. "P" vial (System 3.6)
 - b. "T" vial (System 3.7)
 - c. "S" vial (System 3.8)
 - d. Waste (System 3.9)
 - e. Sample well (System 3.3)
 - f. Dilution well (System 3.4)
 - g. Cuvette (System 3.5)

When the display shows [ADJUST POSITION], press 0 to move the boom arm left or • to move the boom arm right. Press **STORE** when the correct boom position has been determined. The boom moves to the next position.

When **STORE** is pressed in both the sample well and the dilution well positions, the probe moves further down into the well. This allows a more accurate adjustment to be made. When **STORE** is pressed the second time, the boom moves to the next position.

8. The probe then dips into each of the five sample wells to determine the correct Z-boom position for the liquid-level sensors.

The display shows [Z-BOOM LEVEL = XXX], where XXX is the step number where liquid was detected. This step number should be 172 or 173.

Press **NEXT** to check all five carousel positions. Record the step number at each position.

The step numbers must not vary by more than one step. Remove cartridge(s) and repipette any outliers before continuing. Reread all five positions by pressing **NEXT**. Return to the carousel position that had the lowest step number and adjust it to step number 172 as follows:

- a. To increase the step number, press **0**.
- b. To decrease the step number, press **.**
- c. When the display shows step 172 with the probe down in the cup, check all other positions by pressing **NEXT**. To recheck a single position, press **CLEAR**.

NOTES: The Z-boom position step number for a single position cannot be changed without affecting the other position step numbers.

In any position where fluid is not detected at a step number of 173 or less, the sample will be skipped during an assay or calibration run.

- d. Verify that no position shows a step number greater than 173, then press **STORE**.
9. When the correct Z-boom home value (System 3.14) is stored in memory, the display returns to [READY].
10. Press **SYSTEM 3 PRINT** to obtain a printout of the new System 3.3 through 3.14 parameters.

NOTE: The boom and carousel positions stored during this procedure cannot be verified by running another boom calibration, doing so would recalibrate rather than verify. To check these positions, perform a buffer run or use the Test 4 hand controls.

Test 3.3 - Carousel Calibration

This test calibrates the carousel home (SYSTEM 3.1 CAR HM) position and ensures that the carousel is centered correctly in the photometer read station when intensity measurements are made. This procedure requires a carousel home alignment tool (not supplied with the TD_x System).

Do not edit the System 3.1 parameter. This calibration is done by an Abbott Field Service Engineer.

Test 3.4 - Photo Calibration

Contact the Customer Support Center **before** performing this procedure.

Photo Calibration is used to calibrate the photomultiplier tube by calculating the correct High Voltage Coefficient (Test 3.4.3) and P Bias values (System 2.5). The performance of this procedure may be necessary to resolve a Photo Check (Test 2.2) failure.

1. Select the Fluorometric Standards Function Test Set Carousel.
2. Locate the label along the side of the inner wall of the carousel. This label lists the gain, intensity, and polarization values for that particular carousel.
3. Press **TEST 3.4 PRINT** and **TEST 2.2 PRINT**.
4. Check the gain, intensity, and polarization parameters on the printout with those marked on the carousel label. Verify that the GAIN in Test 2.2.1 agrees with the carousel label.
5. If any of the values do not match, press **TEST 3.4.X EDIT** and/or **TEST 2.2.1 EDIT** (enter the number from the carousel) **STORE STOP**.
6. Print out the new values and ensure that the parameters match those on the carousel.
7. Place the Fluorometric Standards Function Test Set Carousel into the instrument. Close the access door.
8. Press **TEST 3.4 RUN**. The date, time, and serial number for the instrument are printed. If the barcode reader is unable to read the carousel label or if the carousel is not a valid Fluorometric Standards Function Test Set Carousel, the display reads [CAR LBL ERR-RUN?].

Press **STOP** if you do not wish to continue. Otherwise, press **RUN**. The display reads [PHO CAL].

The calibration routine requires from 10 to 30 minutes. When completed, the high voltage coefficient and P Bias values followed by PASS are printed. The new high voltage coefficient and P Bias values are stored in permanent memory.

The TD_x® System returns to [READY].

If the test does not pass, an error message displays and prints. The test should be repeated. Refer to Section VI, Troubleshooting, for assistance.

9. When the test passes, run a Photo Check procedure (Test 2.2). Use the same Fluorometric Standards Function Test Set Carousel for the Photo Check procedure that was used for Photo Calibration. The operator may designate the Fluorometric Standards Function Test Set Carousel(s) for use with specific analyzer serial number(s) by placing a serial number label on the inner ring opposite the factory-installed carousel label. See Section V, Maintenance. Photo Check values should fall within these ranges:

Average Intensity $\pm 12\%$ of the carousel labeled value

Intensity Range ≤ 600

Average Polarization ± 1.5 mP of carousel labeled value

Polarization Range ≤ 2.5 mP

If the Photo Check does not meet these specifications, rerun the Photo Calibration and Photo Check procedures. If the values are still out of range, contact the Customer Support Center.

Test 3.5 - Z-Boom Calibration

Z-boom Calibration determines the correct liquid-level sensing position for the vertical (Z) boom (SYSTM 3.14 ZBM HM) only, and automatically stores this position in memory.

1. Place sample cartridges in positions 1, 5, 10, 15 and 20 of an assay or calibration carousel.
2. Accurately pipette 50 μ L of X SYSTEMS™ Dilution Buffer into the sample well of each sample cartridge. Pipette the buffer directly into the bottom of the sample well.
3. Place the carousel into the instrument. Leave the access door open.
4. Press **TEST 3.5 RUN**. The display reads [Z-BOOM CAL]. The probe then dips into each of the five sample wells to determine the correct Z-boom position for the liquid-level sensor.

The carousel will return to position 1 and the display reads [Z-BOOM LEVEL = XXX], where XXX is the step number of the Z-boom where liquid was detected. This step number should be 172 or 173.

Check all five carousel positions by pressing **NEXT**. Record the step number at each position.

The step numbers must not vary by more than one step. Remove cartridge(s) and repipette any outliers before continuing. Reread all five positions by pressing **NEXT**. Return to the carousel position that had the lowest step number and adjust it to step 172 as follows:

- a. To increase the step number, press 0.
- b. To decrease the step number, press •.
- c. When the display shows step 172 with the probe down in the cup, check all other positions by pressing **NEXT**. To recheck a single position press **CLEAR**.

NOTES: The step number for a single position cannot be changed without affecting the other position step numbers.

In any position where fluid is not detected at a step number of 173 or less, the sample will be skipped during an assay or calibration run.

- d. Verify that no position shows a number greater than 173, then press **STORE**.
5. The new Z-boom value is stored in memory and the display reads [READY].
6. Press **SYSTEM 3 PRINT** to obtain a printout of the parameters. The 3.14 ZBM HM (vertical boom home) parameter will have been calibrated.

Test 3.6 - Unit Dose Boom Calibration

The Unit Dose Boom Calibration (Test 3.6) must be performed after changing the probe.

The Unit Dose Boom Calibration procedure is described below.

NOTE: The Unit Dose Boom Calibration should be performed only after a Boom Calibration (Test 3.2) has been performed.

1. Insert a unit dose cartridge with cuvette attached, into position 1 of a unit dose calibration carousel. Lock the cartridge into position.
2. Pipette a minimum of 50 μ L of X SYSTEMS™ Dilution Buffer into the sample well of the unit dose cartridge.
3. Place the carousel into the instrument. Leave the access door open.
4. Press **TEST 3.6 RUN**. The display reads [U.D. CAL CAROUSEL] if using a unit dose calibration carousel or [U.D. CAROUSEL] if using a unit dose assay carousel.

NOTE: If a [BARCODE FAIL] occurs and you want to continue the boom calibration using this carousel, press **NEXT**. The messages [CK CAROUSEL READ] and [CONTINUE?] appear. Press **STORE**. The calibration continues to step 5.

5. When [SYS 3 PARAMS OK?] appears in the display, the system is asking if a boom calibration has been performed in the batch mode of operation. If it has, press **STORE**. [U.D. BOOM CAL] displays. The carousel rotates, stops, and positions the probe over the cuvette.

NOTE: If a batch mode Boom Calibration has not been performed, press **STOP** and perform the batch mode Boom Calibration (Test 3.2).

6. When [ADJUST POSITION] appears in the display, center the probe in the cuvette position. Press **•** to move the boom arm one step to the right. Press **0** to move the boom arm one step to the left. Press **STORE** when the probe is centered in the cuvette position.
7. The probe moves further down into the cuvette. If further adjustment is required to center the probe, press the **•** key to move the probe to the right and the **0** key to move it to the left. Press **STORE** when the probe is centered.

-
8. The probe then moves to the "T" well. Press keys **•** and **0** to center the probe over the well. Press **STORE** when centered.
[U.D. BOOM CAL] displays.

9. The barcode reader locates and reads the barcode on the unit dose cartridge. When the assay name is displayed, press **STORE** if the name is correct.

If the assay name displayed is incorrect, perform the following steps:

- a. Press **PRIME** to turn the barcode reader lights on.
- b. Press **0** to move the barcode reader left or **•** to move it right, as needed, to center the barcode reader over the unit dose cartridge barcode.
- c. Press **6** to move the carousel clockwise or **3** to move it counterclockwise until the brighter of the two barcode reader lights is approximately 1/8 of an inch in front of the start of the cartridge barcode label.
- d. When the barcode reader lights are properly centered in front of the cartridge barcode label, press **DISPLY** three times to read the present cartridge barcode label three times. If the assay name displayed all three times is correct, press **STORE**. (If the assay name displayed is not correct, call the Customer Support Center.)

NOTE: At this point, Unit Dose Boom Calibration is complete and the display reads [READY].

10. Press **SYSTM 8 PRINT** and **SYSTM 3 PRINT** to obtain printouts of the parameters. Keep a copy of these printouts for future reference.

Test 3.7 - 4 - Pot Reagent Pack Boom Calibration

The 4-Pot Reagent Pack Boom Calibration (Test 3.7) must be performed prior to running any 4-pot reagent pack assays for the first time, and also after performing the Boom Calibration (Test 3.2) procedure.

4-Pot Reagent Pack Boom Calibration is described below.

NOTE: The 4-Pot Reagent Pack Boom Calibration procedure should be performed only after a Boom Calibration (Test 3.2) has been performed.

1. Remove the vial caps and place a 4-pot reagent pack into the TD_x analyzer. Leave the access door open.
2. Press **TEST 3.7 RUN**. The display will read [4-POT - BOOM CAL]. The instrument searches for the barcode on the reagent pack.

NOTE: If the barcode label is not successfully read, the message [NO TRANSITION PT] appears in the display for 5 seconds. The display then changes to [CONTINUE?]. Press **STOP** to abort the test, or **STORE** to continue the test. The calibration continues to step 3.

3. When [ADJUST POSITION] appears in the display, center the probe over the "P" vial. Press **•** to move the boom arm one step to the right. Press **0** to move the boom arm one step to the left. Press **STORE** when the probe is centered over the "P" vial.
 4. Repeat the process described in Step 3 for the "T", "S", and "W" vials.
 5. After the new R-boom values for SYSTM 3.15, 3.16, 3.17, and 3.18 are stored in memory, the display reads [READY].
 6. Press **SYSTM 3 PRINT** to obtain a printout of the parameters.
-

Test 3.8 - Turbo Carousel Calibration

This diagnostic test is used for Turbo[®] Specific Protein assays. Refer to the TDxFLx[®] & TD_x Turbo Operation Supplement for the procedure.

**Test 4 -
Hand Controls**

CAUTION: THE HAND CONTROLS SHOULD BE USED ONLY BY AN ABBOTT TRAINED OPERATOR OR WITH THE ASSISTANCE OF THE CUSTOMER SUPPORT CENTER.

Test 4 allows the operator to control the mechanical operation of all stepper motors and monitor the status of the optical, temperature control, and barcode systems. These tests do not make any permanent changes in system memory.

Each test uses the keypad to control specific functions or monitor specific parameters.

The display shows various status information to assist the operator during use of the test.

To obtain a listing of these tests, press **TEST 4 PRINT**. The following diagnostic tests are printed:

Test 4.1 - REVOLVER (Carousel movement)

Test 4.2 - PHOTOMETER (Optics Assembly)

Test 4.3 - PUMPER (Dispenser Assembly)

Test 4.4 - BOOMER (Boom Arm Movement)

Test 4.5 - TEMP HNDLR (Temperature System)

Test 4.6 - BARCODE CHK (Barcode Check)

Test 4.1 - Revolver

The carousel and R-boom (horizontal) stepper motors can be controlled using this test. To activate this test, press **TEST 4.1 RUN**. Use the keys on the right side of the keypad to control the R-boom movement and the keys on the left side to control the carousel movement.

- To activate revolver test:

Press **TEST 4.1 RUN**.

NOTE: If the R-boom control has been activated, the carousel control can be regained by pressing 7.

- To control carousel movement:

1. Press **7** to activate carousel control.

Three messages are displayed:

[HC = H or N] - indicates the carousel is at the home (H) position or not at the home position (N).

[C = Y or N] - indicates that the cuvette or carousel locking tab is being sensed by the optical sensor (Y), or that they are not being sensed (N).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the carousel stepper motor has moved to reach the present position.

NOTE: One tab (TB) is equal to 86 steps for the carousel stepper motor. The tab number indicates which carousel location is presently at the dispense axis.

Example: (TB=1) indicates that the sample cartridge in location 1 is at the dispense axis.

2. When [S=] is displayed and **1** or **4** is pressed, the stepper motor moves one step. When [TB=] is displayed and **1** or **4** is pressed, the stepper motor moves 86 steps.

- To control R-boom movement:

1. Press **9** to activate R-boom control. Three messages are displayed:

[HR = H or N] - indicates whether the R-boom is at the home (H) position or not at the home position (N).

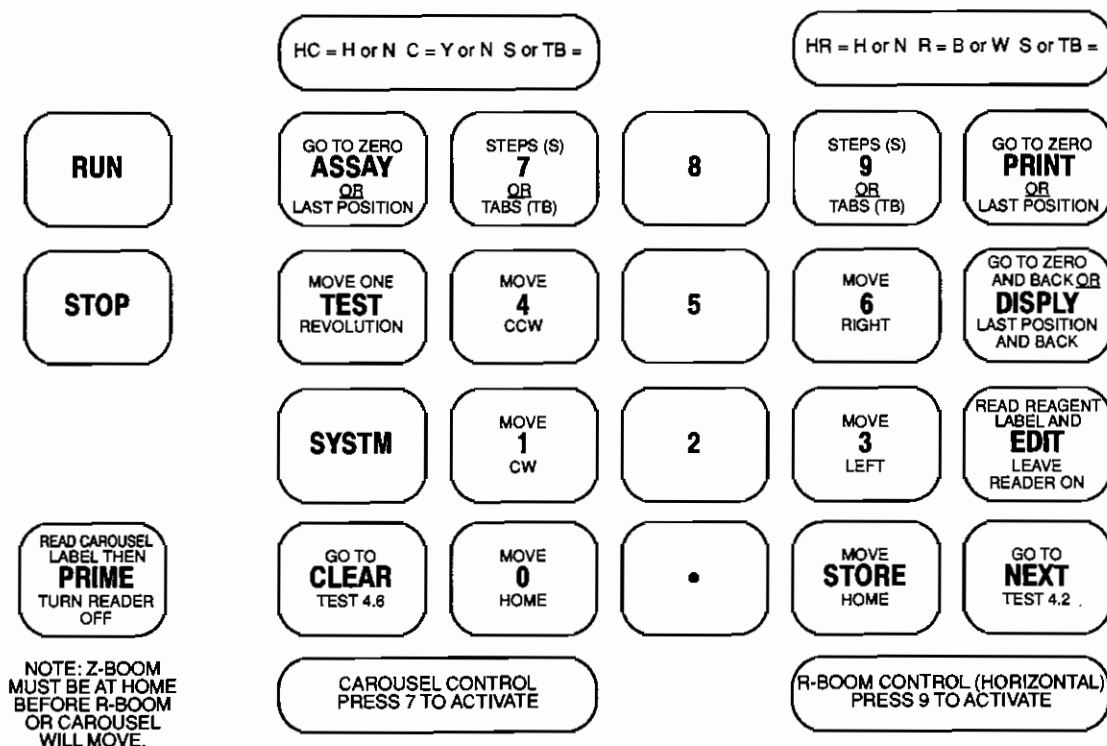
[R = B or W] - indicates the barcode reader is detecting black (B) or white (W).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the R-boom stepper motor has moved to reach the present position. One tab (TB) is equal to 30 steps for the R-boom stepper motor.

If the carousel control is at (TB=) , you enter R-boom control at (S=). The reverse is also true.

CAUTION: TO AVOID DAMAGING THE PROBE, THE Z-BOOM MUST BE AT HOME BEFORE YOU CAN MOVE THE R-BOOM OR THE CAROUSEL (USE TEST 4.4 TO HOME Z-BOOM OR PRESS STOP PRIME).

2. When **EDIT** is pressed, the barcode reader is turned on and the boom arm moves to the position designated as the start of the reagent pack barcode and reads the label. The display shows [BAR AMPL] followed by a number. This number should be greater than 20 and display the correct assay name to indicate that the reader is detecting the label correctly. The display alternates between the pack label name and the amplification value.
3. When [S=] displays and **6** or **3** is pressed, the stepper motor moves one step. When [TB=] displays and **6** or **3** is pressed, the stepper motor moves 30 steps.
4. When [S=] displays and **3** or **6** is pressed, the appropriate stepper motor will move one step. The step number in the display **does not** update until the key is released. If you wish to move the motor one step at a time when moving the R-boom or carousel to a particular step location, release the key quickly after pressing it.



**TEST 4.1
CAROUSEL**

5. The **PRIME** key is active only during R-boom control when [HR=] is displayed. The carousel label is read when this key is pressed, and the display shows [BAR AMPL] followed by a number greater than 20. The display then alternates between the carousel label number and the amplification value. (The Fluorometric Standards Function Test Set Carousel reads 13, a calibration carousel reads 14, a unit dose calibration carousel reads 15 and a unit dose assay carousel reads 16.)

NOTE: The **ASSAY**, **TEST**, **PRINT**, and **EDIT** keys each control two actions. The action depends on the present location of the stepper motor. If the stepper motor is at zero when the key is pressed, the second action occurs. If the stepper motor is not at zero when the key is pressed, the first action occurs.

6. Press **STOP** to return to [READY].

Test 4.2 - Optics Assembly

This test allows the voltage of the PMT, source lamp, and high voltage (HV) power supply to be displayed. The operator can also turn the lamp on and off, change the voltage to the HV power supply, and change the orientation of the polarized light with the appropriate keys.

- To activate this test, press **TEST 4.2 RUN**.

The display reads [PHOTOMETER]. When this test is entered, the integration time is automatically set to 100 msec and the high voltage is automatically set to half scale (500).

The desired measurement can be obtained by pressing the appropriate key (see keypad functions for Diagram 4.2).

- Once a voltage key is pressed, the **left** side of the display shows which system has been selected through the keypad:
 - “PMT” - photomultiplier tube voltage
 - “TIME” - integration time
 - “LMP” - source lamp voltage
 - “HV” - high voltage power supply

- The **center** of the display shows the numeric value for the system selected through the keypad.
- The **right** side of the display shows the **current** status of two items:
 1. The orientation of the polarized light:
 - H = horizontal
 - V = vertical
 2. Status of lamp:
 - * = lamp on
 - (blank) = lamp off

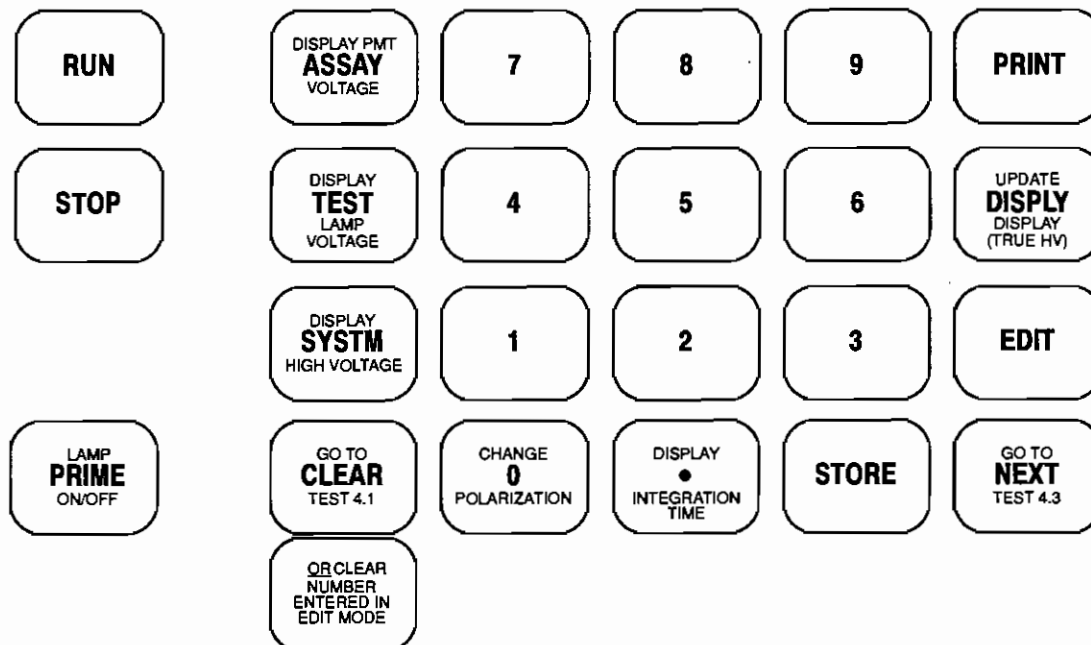
To turn the lamp on, press **PRIME**.

3. When the PMT voltage is displayed, the letter N or U indicates:

N = the lamp is on and the PMT voltage has been normalized (N) by dividing the lamp reference voltage into the PMT voltage.

U = the lamp is off and the PMT voltage is unnormalized (U).

4. Press **STOP** to return to [READY].



TEST 4.2 PHOTOMETER

Test 4.3 - Dispenser Assembly

The dispenser system can be controlled using this test. The keypad is divided into a left and right side. The keys located on the left side of the keypad control the diluent syringe while the keys on the right side control the sample syringe. (See Diagram 4.3 for keypad functions of the diluent syringe and sample syringe control.)

- Press **TEST 4.3 RUN** to activate control of the syringes.
- Press **7** to activate diluent syringe control.

NOTE: If the sample syringe control is activated, diluent syringe control can be regained by pressing **7**.

CAUTION: BEFORE MOVING THE SYRINGES, PLACE A TEST TUBE OR OTHER RECEPTACLE UNDER THE PROBE. THIS PREVENTS SPILLS INSIDE THE SYSTEM.

When diluent syringe control is activated, the display shows three status messages:

[HD = H or N] - indicates that the diluent syringe is at the home (H) position or not at the home position (N).

[V = H or N] - indicates that the valve is at the home (H) position or not at the home position (N).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) that the stepper motor has moved to reach the present position. One tab (TB) is equal to 30 steps.

- Press **9** to activate sample syringe control. The display shows three status messages:

[HS = H or N] - indicates that the sample syringe is at the home (H) position or not at the home position (N).

[B = Y or N] - indicates that the buffer platform is activated (Y) or not activated (N). (When there is sufficient buffer to run an assay, the microswitch is activated.)

[S= or TB=] - indicates the number of steps (S) or tabs (TB) that the stepper motor moved to reach the present position. One tab is equal to 30 steps. If the diluent syringe control was at (TB=), you enter sample syringe control at (S=). The reverse is also true.

CAUTION: BEFORE MOVING THE SYRINGES, PLACE A TEST TUBE OR OTHER RECEPTACLE UNDER THE PROBE. THIS PREVENTS SPILLS INSIDE THE SYSTEM.

NOTE: For Test 4.3 the ASSAY, TEST, PRINT and EDIT keys each control two actions. The action depends on the present location of the syringe plunger. If the plunger is at zero, the second action occurs when the key is pressed. If the plunger is not at zero, the first action occurs when the key is pressed.

Press **STOP** to return to [READY].

| | | | |
|--------------|---|---|---------------------------------------|
| | HD = H or N V = H or N S or TB = | | HS = H or N B = Y or N S or TB = |
| RUN | GO TO ZERO ASSAY OR LAST POSITION | STEPS (S) 7 OR TABS (TB) | 8 |
| | GO TO ZERO TEST OR LAST POSITION & BACK | MOVE 4 DOWN | 5 |
| STOP | SYSTM | MOVE 1 UP | 2 |
| | GO TO ZERO CLEAR TEST 4.2 | MOVE 0 HOME | • |
| PRIME | | MOVE 3 UP | 6 |
| | | GO TO ZERO EDIT OR LAST POSITION & BACK | 9 |
| | | GO TO ZERO PRINT OR LAST POSITION | DISPLY |
| | | GO TO ZERO STORE HOME | DISPLY |
| | | GO TO NEXT TEST 4.4 | |
| | DILUENT SYRINGE PRESS 7 TO ACTIVATE | | SAMPLE SYRINGE PRESS 9 TO ACTIVATE |

NOTE: BEFORE MOVING SYRINGES PLACE A TUBE UNDER THE PROBE TO PREVENT BUFFER SPILLS INSIDE INSTRUMENT.

**TEST 4.3
DISPENSER**

Test 4.4 - Boom Arm Movement

The horizontal (R-boom) and vertical (Z-boom) movement of the boom arm and the reading of unit dose cartridge barcodes can be controlled with this test. The keys located on the left side of the keypad control the R-boom (horizontal) movement while the keys on the right side of the keypad control the Z-boom (vertical) movement. (See Diagram 4.4 for keypad functions for the R-boom movement, Z-boom movement and unit dose barcode.)

- Press **TEST 4.4 RUN** to activate control of boom-arm movement.
- Activate R-boom (horizontal) control as follows:
- Press **7**.

NOTE: If the Z-boom control is activated, R-boom control can be regained by pressing **7**.

When in control of the R-boom, the display shows three status messages:

[HR = H or N] - indicates that the R-boom is at the home (H) position or not at the home position (N). HR appears to the left of the H or N to indicate that the R-boom control is active.

[R = B or W] - indicates that the barcode reader is detecting black (B) or white (W).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the stepper motor moved to reach the present position. One tab is equal to 30 steps.

- Activate Z-boom (vertical) control as follows:
 1. Press **9**. When in control of the Z-boom, the display will show three status messages:

[HZ = H or N] - indicates that the Z-boom is at the home (H) position or not at the home position (N). HZ appears to the left of the H or N to indicate that the Z-boom control is active.

[L = Y or N] - indicates that the fluid sensing electrodes are sensing liquid (Y) or not sensing liquid (N).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the stepper motor moved to reach the present position. One tab is equal to 30 steps. If the R-boom control is at (TB=), you will enter Z-boom control at (S=). The reverse is also true.

CAUTION: Z-BOOM MUST BE AT HOME BEFORE THE R-BOOM OR CAROUSEL CAN BE MOVED. TO RETURN THE Z-BOOM TO HOME, PRESS KEYS **9** AND **STORE**.
 2. Press **STOP** to return to [READY].

- Activate unit dose cartridge barcode control as follows:
 1. Press **8** when the display reads [HR=]. The display changes to:

U.D. BARCODE

2. Press **5**. The System reads the unit dose cartridge barcode in position 1. The display alternates between:

ASSAY NAME

and

BAR AMPL #

3. Press **2**. The next unit dose cartridge barcode is read. You can advance the carousel but you cannot reverse it.
4. To reread the same cartridge, press **•**.
5. Press **STOP** to return to [READY].

| | | | | | |
|--|---|--|--|--|---|
| | HR = H or N R = B or W S or TB = | U.D. BARCODE | HZ = H or N L = Y or N S or TB = | | |
| RUN | GO TO ZERO ASSAY OR LAST POSITION | STEPS (S) 7 OR TABS (TB) | ACTIVATES UNIT DOSE 8 BARCODE | STEPS (S) 9 OR TABS (TB) | GO TO ZERO PRINT OR LAST POSITION |
| STOP | GO TO ZERO & BACK OR TEST LAST POSITION & BACK | MOVE 4 RIGHT | READ U.D. CARTRIDGE 5 BARCODE CAROUSEL POSITION 1 | MOVE 6 DOWN | MOVE DOWN TO LLS OR DISPLY MOVE TO BOTTOM |
| | READ REAGENT LABEL AND SYSTM LEAVE READER ON | MOVE 1 LEFT | READ NEXT 2 U.D. CARTRIDGE BARCODE | MOVE 3 UP | GO TO ZERO AND BACK EDIT OR LAST POSITION & BACK |
| READ CAROUSEL LABEL AND PRIME TURN READER OFF | GO TO CLEAR TEST 4.3 | MOVE 0 HOME | REREAD CURRENT • U.D. CARTRIDGE BARCODE | MOVE STORE HOME | GO TO NEXT TEST 4.5 |
| NOTE: Z-BOOM MUST BE AT HOME BEFORE R-BOOM WILL MOVE. | R-BOOM CONTROL (HORIZONTAL) PRESS 7 TO ACTIVATE | | Z-BOOM CONTROL (VERTICAL) PRESS 9 TO ACTIVATE | | |

**TEST 4.4
BOOM ARM**

NOTES: The ASSAY, TEST, PRINT, DISPLY and EDIT keys each control two actions. The action depends on the present location of the boom arm. If the boom arm is at zero when the key is pressed, the second action occurs. If the boom arm is not at zero when the key is pressed, the first action occurs.

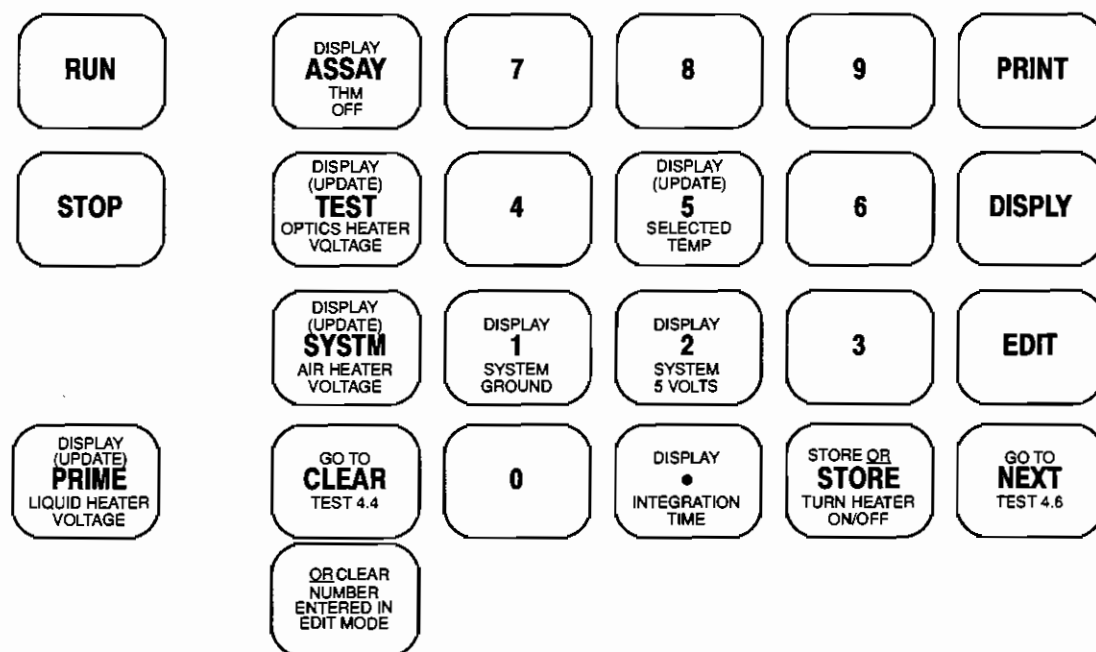
When [S] is displayed and keys 1, 3, 4 or 6 are pressed, the appropriate stepper motor will be moved one step. The step number in the display **does not** update until the key is released. If it is desired to move the motor one step at a time when you are moving the R-boom or Z-boom to a particular step location, release the key quickly after pressing.

The 8 key is active only during R-boom control. Pressing 8 activates the ability of the barcode reader to locate the unit dose cartridge barcode.

Test 4.5 - Temperature System

This diagnostic test allows the operator to display the voltage and temperature of the three heater systems by pressing the appropriate key. The ground, thermopile and 5-volt values can also be displayed by pressing the appropriate keys.

- Activate the temperature system as follows:
 1. Press **TEST 4.5 RUN**. The display reads [TEMP HNDLR]. When this test is entered, the integration time is automatically set to 100 msec.
 2. Press the appropriate key (see keypad functions for Diagram 4.5) to determine the desired measurements.



**TEST 4.5
TEMPERATURE**

- The left side of the display shows which system has been selected:
 - “THMO” - thermopile voltage
 - “OPT” - optics heater
 - “AIR” - air heater
 - “LIQ” - liquid heater
 - “SYS GND” - system ground voltage
 - “SYS 5V” - system 5V voltage reading
- The center of the display shows either the voltage [V=] or the temperature [T =] of the selected system.
- The right side of the display indicates whether the selected heater system is ON or OFF. The STORE key temporarily turns the heater on or off; however, the change does not show until the display is updated by pressing 5.
 3. To display the temperature of a heater system, press the appropriate key for the heater voltage, then press 5.
 4. Press **STOP** (press **CLEAR** first if editing) to return to [READY].

Test 4.6 - Barcode Check

The barcode reader can be turned on and off with this test and the DAC (digital-to-analog converter) reading will be displayed. The DAC transition point from black to white can be temporarily set. The test can also be used to confirm that black or white is being detected correctly according to the DAC setting. The test is useful to determine whether a reagent pack barcode label is being read consistently across the full length of the label.

- To activate the barcode reader:
 1. Press **TEST 4.6 RUN**. The display will show three status messages:
 - [S=] - indicates the last DAC value entered by the operator (set point).
 - [R=] - indicates the last DAC value read by the barcode reader.
 - [B=] - indicates whether the barcode reader is detecting black (Y) or not detecting black (N).
 2. Press **PRIME** to turn the barcode reader on. Manually move the barcode reader so the red dots are just to the left of the first black bar on the reagent pack label or just in front of the first black bar on the carousel label.
 3. Press **DISPLY** and record DAC reading (R=XXX) as the white value.
 4. Manually move the barcode reader so both red dots are over the first black bar on the reagent pack label or carousel label.
 5. Press **DISPLY** and record the DAC reading (R=XXX) as the black value.

6. Calculate the set point as follows:

$$\text{SET POINT} = \frac{\text{WHITE VALUE} + \text{BLACK VALUE}}{2}$$

Enter the set point by pressing the appropriate numerical keys. The left side of the display shows the entered set point as [S=].

7. Move the barcode reader over the other portions of the label and check the updated DAC reading by pressing **DISPLY**. The DAC reading should be below the set point when the barcode is over black and the right side of the display shows [B=Y]. The DAC reading should be above the set point when the barcode is over white and the right side of the display shows [B=N].

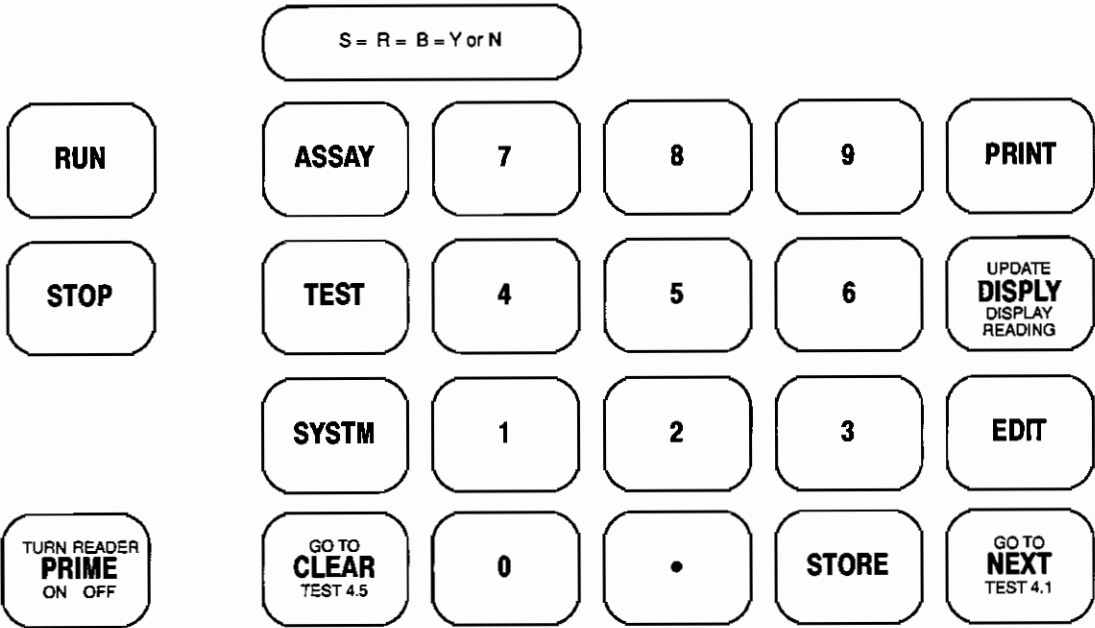
NOTES: The **PRIME** key turns the barcode reader on or off. The **DISPLY** key updates the DAC reading. All the numerical keys are active and are used to enter a DAC value. The numbers pressed appear in the display to the right of [S=].

When Test 4.1 or Test 4.4 is used to read a label, the [BAR AMPL] reading that is displayed will equal approximately $\frac{1}{2}$ the difference between the DAC reading when the barcode reader is over the white and the DAC reading when the barcode reader is over the black portion of the label.

$$\text{BAR AMPL} = \frac{\text{WHITE VALUE} + \text{BLACK VALUE}}{2}$$

The DAC reading from the white part of the label should be at least 20 greater than the DAC reading from the black part of the label. If the reading difference is not 20 on several reagent packs, clean the barcode reader. If cleaning does not correct the problem, the barcode reader height needs an adjustment. Contact the Customer Support Center.

If the DAC readings across the pack vary so much that the barcode does not detect black or white correctly, the problem is most likely due to a crooked reagent pack insert, a dirty label, a warped pack, or the barcode reader is swinging unevenly due to an improper boom arm alignment.



TEST 4.6
BARCODE CHECK

Test 5 - Board Tests

Diagnostic tests for the boards are designed to verify board integrity. Do not perform these tests without first contacting the Customer Support Center.

- | | | |
|------|-------|---|
| Test | 5.1 | REPEAT RUN - Runs all Test 5 programs continuously, except for front panel, long print, motor board, and UART tests. |
| | 5.1.1 | SINGLE RUN - Starts at the beginning of Test 5 and executes one test at a time, except for front panel, motor board, and UART tests. |
| Test | 5.2 | COMPUTER BOARD |
| | 5.2.1 | PROM TEST |
| | 5.2.2 | RAM TEST |
| Test | 5.3 | Memory Board 1 |
| | 5.3.1 | PROM TEST 1 |
| | 5.3.2 | NOVRAM TEST 1 |
| Test | 5.4 | PRINTER & DRIVER |
| | 5.4.1 | LONG PRINT TEST - prints 10 rows of all printhead pins across the paper. |
| | 5.4.2 | SHORT PRINT TEST - prints one row with each of the seven printhead pins individually. |
| Test | 5.5 | I/O BOARD (Input/Output Board) |
| | 5.5.1 | UART TEST - requires loop back connector. |
| | 5.5.2 | CTC TEST (Counter-Timer Circuit Test) |
| Test | 5.6 | FRONT PANEL |
| | 5.6.1 | KEYBOARD TEST - checks each key on keyboard and displays value of the key. Press STOP twice to end test. |
| | 5.6.2 | DISPLAY TEST - checks all dots of the front panel display. |
| Test | 5.7 | MTR BOARD (motor board) - checks the sensors and motors on the triple motor (motor driver) boards. This routine also checks part of the analog/optics board related to the optics system. |

**Test 6 -
Special Tests**

With the exception of Dispense Check (Test 6.3) and Turbo Correction Factor Entry (Test 6.4), these tests are intended for factory testing and service ONLY. None of these tests should be performed without first consulting the Customer Support Center. Otherwise, damage to the instrument could result.

6.1 MEMORY BD NOV RAM

6.2 FACTORY SET

6.3 DISPENSE CHECK

6.4 TURBO® ENTRY

6.5 ZERO CALIB CURVE

6.6 PRINT ALL PARAMS

6.7 F.T. CALC

**Test 6.3 -
Dispense Check**

Test 6.3 can be used to observe many modes of pipetting (selected by the assay used) for splashing, carryover, probe positioning, or to check for any possible problems in the pipetting sequence. This test performs only Rev 1 and Rev 2 pipetting with a 5 second pause between them. The Dispense Check does not include Rev 0 pipetting, cuvette counting, barcode reading, or intensity reading. All pots (reagents, sample, and predilute) are checked for LLS error. Up to 15 cuvettes may be run.

Do not run the Dispense Check procedure on pipetting modes that include Rev 0 pipetting (3, 7, 10, 23, 27, 31, 40 and 42). To determine the pipetting mode for a specific assay, press **ASSAY XX.18 DISPLY**.

The procedure for Test 6.3 is described below.

1. Load a carousel with the appropriate number of sample cartridges and cuvettes. Since there is no cuvette counting in this procedure, be certain to have a cuvette for each sample cartridge.
2. For the assay being simulated, pipette the appropriate sample volume of X SYSTEMS™ Dilution Buffer into each sample well. For example, a minimum of 250 µL of buffer should be used for Assay 10, Digoxin II.
3. Place a reagent pack containing X SYSTEMS Dilution Buffer into the TD_x System.

-
4. Place the carousel into the TD_x System. Leave the access door open.
 5. Press **TEST 6.3 RUN**.
 6. The system displays:

ASSAY NUMBER _ _

Refer to the reference assay list printout for the number of the assay required. If list is not available, press **ASSAY PRINT**.

Enter the two digit number for the assay required. Press **STORE**.

7. The display shows the assay name.
8. Test 6.3 then performs Rev 1 pipetting. The display reads:

REV 1 PIPETTING

9. At the completion of Rev 1 pipetting the system performs Rev 2 pipetting. The display reads:

REV 2 PIPETTING

10. When the system completes Rev 2 pipetting for all samples, the pipetting sequence stops. The display reads:

READY

Test 6.4 - Turbo Correction Factor Entry

This test is used for Turbo[®] Specific Protein assays. Refer to the TDxFLx[®] & TD_x Turbo Operation Supplement for additional information.

**Observation of
Dispense Process****“BUFFER RUN”**

Purpose: To observe the dispensing process of the TD_x® System, noting probe position in the sample well, and the predilution well. Also to observe mixing action in the predilution well. This procedure differs from the Dispense Check (Test 6.3) in that all initial checks are performed by the TD_x System.

1. Place the reagent pack, with vial caps removed, into the instrument. An empty reagent pack, with buffer placed in the vials, should be used.
2. Prepare a carousel with several sample cartridges and cuvettes, then pipette X SYSTEMS™ Dilution Buffer into the sample wells. Place the carousel into the instrument. (A minimum volume of buffer specified for the selected assay may be used if troubleshooting a sample skipping problem or verifying that a minimum fluid volume will be sensed.)

Refer to the appropriate assay manual insert for minimum sample volume values.

3. Disable the door lock sensor:
 - a. Ensure the display is at [READY].
 - b. Press **SYSTEM 2.2 EDIT 0 STORE**.
 - c. Press **STOP** to return to [READY].
4. Leave the access door open and press **RUN**. If a particular assay requires observation, initiate that assay using the Barcode Override procedure described in Section III.
5. Observe the dispensing operation for the following:
 - a. Splashing in the predilution well.
 - b. Foaming in the predilution well.
 - c. Probe properly centered in the sample well.
 - d. Probe properly positioned in the predilution well.

If splashing and foaming are observed, carefully check the condition and position of the probe as described in Section V, Maintenance, under Probe Inspection and Probe Positioning Check and Adjustment using the probe positioning cartridge.

6. Enable the door lock sensor:
 - a. Ensure the display is at [READY].
 - b. Press **SYSTEM 2.2 EDIT 1 STORE**.
 - c. Press **STOP** to return to [READY].

**Coefficient of Variation
(CV) Check**

The purpose of this procedure is to check the within-run reproducibility of the TD_x System.

1. Load an assay carousel with 10 replicates of each of two levels of controls.
2. Place the appropriate reagent pack, with vial caps removed, and the carousel into the instrument.
3. Close access door and press **RUN**.
4. At the completion of the assay, calculate the mean (\bar{x}) and standard deviation (SD) for each level of control for both polarizations (P) and concentration results.
5. Calculate the % CV for the concentration results on both levels of controls.

$$\% \text{ CV} = 100 \times \frac{\text{SD}}{(\bar{x})}$$

Specifications for acceptability:

- a. Concentration mean within range stated in the assay manual insert.
 - b. Concentration CV as stated in the appropriate assay section of the assay manual insert.
6. If results are not acceptable, refer to the Observed Problems under Erratic Test Results in Section VI, Troubleshooting.

Background Subtraction Check

To verify that backgrounds are properly subtracted, follow the procedure below:

1. Place 12 sample cartridges and cuvettes into an assay carousel and lock the cuvettes into position.
2. Add a minimum of 50 μL of the selected assay A calibrator to the sample wells of sample cartridges 1 and 2.
3. Add a minimum of 50 μL of X SYSTEMS™ Dilution Buffer to the sample wells of sample cartridges 3 through 7.
4. Add a minimum of 50 μL of Pipet Check Solution to the sample wells of sample cartridges 8 through 12.
5. Place the selected assay reagent pack, with vial caps removed, and the carousel into the instrument. Close the access door, and press **RUN**. At the completion of the assay, results should be as follows:

| | <u>BLK I Results</u> | <u>NET P Results</u> |
|-----------------|---------------------------------|--|
| Cuvettes 3 - 7 | Low values | Same as AVG P for A Calibrator for selected assay ± 5 mP |
| Cuvettes 8 - 12 | High values | Same as AVG P for A Calibrator for selected assay ± 5 mP |

6. If results are not within the stated limits, contact the Customer Support Center.

**Probe Performance -
Carryover Check**

This diagnostic test checks the carryover of the probe. Carryover of 1.5% or less indicates the probe is performing properly.

1. Ensure there is a valid calibration curve stored in memory for the assay suspected of carryover.
2. Place 5 sample cartridges and cuvettes into an assay carousel and lock the cuvettes into position.
3. Load the appropriate controls into the sample wells as shown in the load list below:

| <u>Position</u> | <u>Contents</u> |
|-----------------|-----------------|
| 1 | L Control |
| 2 | L Control |
| 3 | L Control |
| 4 | H Control |
| 5 | L Control |

4. Remove the vial caps and place the appropriate reagent pack into the instrument.
5. When the results are obtained, determine the percent carryover (% c.o.) as described below:

Carryover (%c.o.) .

- a. Average the results from positions 1, 2 and 3.
- b. Calculate carryover from this formula:

$$\% \text{ c . o . } = \frac{(\text{pos . 5 result}) - (\text{average of positions 1, 2 and 3 results})}{(\text{position 4 result})} \times 100$$

If the carryover is more than 1.5%, wash and dry the probe and repeat the Probe Performance - Carryover Check.

If the carryover is still more than 1.5%, replace the probe.

Introduction

This section details the maintenance requirements for the TD_x System. Procedures for additional adjustments/checks and component replacement are also provided.

MAINTENANCE**Daily**

- Empty Waste Container
- Inspect and Wash Probe
- Dispenser Assembly Inspection
- Unit Dose Probe Position Verification (if applicable)

Weekly

- Clean Carousels
- Dispenser Water Wash
- Clean Air-Fan Filter
- Photo Check

Monthly

- Pipet Check
- Precision Dispenser Calibration
- Temperature Check
- Diluent Syringe Wash

Quarterly

- Printer (cleaning/lubrication)
- TD_x Centrifuge Speed Check
- TD_x Centrifuge Speed Calibration

Perform as Needed

- Barcode Reader Cleaning
- Carousel Home Sensor Cleaning
- TD_x Centrifuge Cleaning and Decontamination
- Circuit Board Cleaning
- Optical or Thermal Sensor Cleaning
- Probe Decontamination Procedure

ADJUSTMENTS/CHECKS

- Barcode Reader Lateral Adjustment Check
- Boom Calibration Verification (refer to Section IV, Test 3.2 for Boom Calibration procedure)
- Buffer Platform Adjustment
- Liquid-Level-Sensing Adjustment
- Probe-Positioning Check and Adjustment (batch and unit dose)

COMPONENT REPLACEMENT

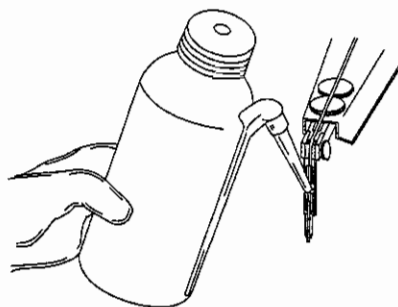
- Access Door
- Buffer
- Circuit Board
- Lamp
- Printer (paper and ribbon)
- Probe/Fluid-Sensing Electrode
- Syringe (diluent and sample)
- Tubing
- Valve Block

| | |
|-------------------------------|--|
| Introduction | Perform daily maintenance procedures at the start of each day or at the start of each 8-hour shift if your system is to be used on multiple shifts. |
| Empty Waste Container | Empty the waste container and rinse thoroughly with water. Return the container to the proper position. |
| Inspect and Wash Probe | <p><u>Probe Inspection</u></p> <ol style="list-style-type: none"> 1. Inspect the probe from the front and the side. The tip should be pointed, not flared. 2. Check the TEFLON® coating on the probe for evidence of chipping or flaking. If the TEFLON coating is chipped or flaked, replace the probe. The coating may show signs of gradual wear on the front. This is normal and typically does not affect probe performance. Unless there are indications that the probe is not functioning properly, i.e., poor duplication or erratic test results, it is not necessary to replace the probe. 3. Inspect the fluid-sensing electrodes. If metal is exposed beyond the taper, replace them according to the procedure in Component Replacement. 4. Prime the system, slightly raising the boom arm so that the fluid stream is barely visible above the top of the waste cup. Inspect the probe for bubble formation, spraying, and a straight liquid stream. 5. If bubbles form at the probe tip, or if liquid sprays outward from the tip, wipe the probe and repeat the priming. 6. If bubble formation is still present, perform the Probe Cleaning procedure, and inspect again during prime. 7. If bubbles persist, replace the probe. |

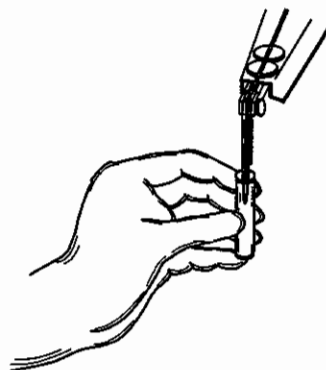
Probe Wash

CAUTION: THE PROBE AND ELECTRODES ARE SHARP AND CONTAMINATED WITH POTENTIALLY INFECTIOUS MATERIALS. AVOID CONTACTING THEM.

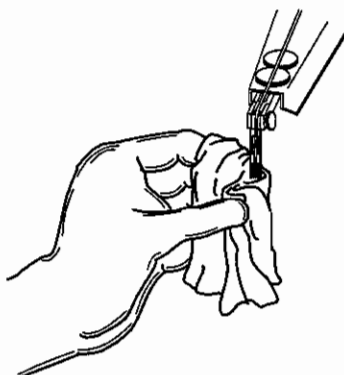
1. Remove the carousel and reagent pack.
2. Manually move the boom arm to the center of the instrument. Do not pull on the probe assembly.
3. Place an absorbent tissue underneath the probe. Rinse the probe by flushing it with distilled water. The water should run from the top of the detent to the bottom of the fluid-sensing electrodes.



4. Fill a small test tube with distilled water and immerse the probe tip into the water. Do not hit the tip of the probe against the test tube.



5. Using a soft, lint-free tissue, blot the probe until it is dry. Ensure that the area between the probe and the fluid-sensing electrodes is dry.



6. To verify that the probe is dry:
 - a. Press **TEST 4.4 RUN 9**.
 - b. The display must read [L = N]. If it does not, repeat Steps 3 through 6.
7. Prime several times to ensure that the tubing is filled with buffer and that the probe returns to its home position.

NOTE: For assays using whole blood, care should be taken to ensure that no dried blood remains on the probe after the wash.

Probe Wash Following REA® Assays

After REA Clinical Chemistry assays are run, the probe may be slightly discolored by the dyes used in the REA reagents. Following each REA assay or calibration run, perform this procedure:

1. Wet a lint-free tissue with distilled water, and gently wipe the outside of the probe and sensor tips. **DO NOT** bend the tip of the probe.
2. Clean the inside the probe by pressing **PRIME** three times.
3. Blot the probe dry with a soft, lint-free tissue. Ensure that the area between the probe and the fluid-sensing electrodes is dry.

Dispenser Assembly Inspection

1. Press **PRIME** three times. Inspect for air bubbles and leaks in all tubing and dispenser connections. (To remove air bubbles, refer to Section VI under Observed Problems).
2. Inspect for dried buffer salts or liquid buffer in and around all dispenser components. Replace as needed.

Unit Dose Probe Position Verification (if applicable)

Verify probe position daily at the completion of a unit dose run. If the puncture marks on the foil are not correct, refer to Adjustments/Checks for the unit dose probe positioning procedure.


| | |
|-----------------------------|---|
| Introduction | <p>These procedures should be performed once a week.</p> <p>Record all maintenance in the TD_x/TD_xFL_x® Maintenance Log.</p> |
| Clean Carousels | <p>Inspect the carousels for dried buffer salts. Rinse with tap water as needed.</p> <p>CAUTION: DO NOT WASH THE CAROUSEL WITH HOT WATER BECAUSE HIGH TEMPERATURES MAY CAUSE DAMAGE. BLEACH SOLUTIONS MAY ALSO CAUSE DAMAGE.</p> |
| Dispenser Water Wash | <ol style="list-style-type: none"> 1. Place the inlet tube into distilled/deionized water. 2. Prime the system five times. 3. Replace the inlet tube into the buffer container. 4. Prime the system five times. |
| Clean Air-Fan Filter | <ol style="list-style-type: none"> 1. Remove the base air-fan filter from the underside (front) of the TD_x System by pulling straight out (toward the operator) on the filter handle. 2. Rinse the filter under running tap water. 3. Blot the filter completely dry. 4. Allow the filter to dry 30 minutes before replacing it into your system. 5. Slide the filter back into the filter bracket with the  or FILTER upright on the edge of the handle. 6. Slide the filter into the space brackets firmly until it comes to a stop. Check to ensure that the air-fan filter is properly seated and the handle is flush with the base of the system. |

Photo Check

The Photo Check procedure helps to ensure photometer/optical system reproducibility.

The Fluorometric Standards Function Test Set Carousel Version II (LN 9520-31) is needed to perform this procedure. Use the same Fluorometric Standards Function Test Set Carousel for the Photo Check procedure that was used for the Photo Calibration procedure.

1. Press **TEST 2.2.1 DISPLY**. Check that the gain value on the Fluorometric Standards Function Test Set Carousel label, located on inner wall of the carousel, agrees with the displayed value. If it does not, edit the parameter by pressing **EDIT** (enter carousel gain) **STORE STOP**. Also, print Test 3.4 parameters by pressing **TEST 3.4 PRINT**. Edit them to agree with the Fluorometric Standards Function Test Set Carousel label, if necessary.
2. Lock the Fluorometric Standards Function Test Set Carousel, and place it in the instrument. It may be necessary to insert an empty cuvette in any unused position of the carousel to keep it locked. Close the carousel access door.
3. Press **RUN** or alternately **TEST 2.2 RUN**, if the Fluorometric Standards Function Test Set Carousel barcode label does not read correctly.
4. When the test is completed (approximately five minutes), the display returns to [**READY**]. An example of a typical photo check printout is presented on the following page.

Using the polarization and intensity values that are given on the Fluorometric Standards Function Test Set Carousel label, the photo check values should fall within the following specifications:

- Average Intensity = $\pm 12\%$ of carousel-labeled value
- Intensity Range = ≤ 600
- Average Polarization = ± 1.5 mP of carousel labeled value
- Polarization Range = ≤ 2.5 mP

Values outside the specified tolerance are flagged as errors. Refer to Photo Check Out of Specification in Section VI, under Observed Problems. Over a period of time, values will eventually trend out of specification due to normal component aging.

PHOTO CHECK

DATE:

TIME:

SERIAL #:

GAIN:

| LOC | INTENSITY | POL |
|------|-----------|-------|
| 1 | 10638.13 | 43.96 |
| 2 | 10543.19 | 46.73 |
| 3 | 10527.56 | 46.84 |
| 4 | 10647.67 | 47.13 |
| etc. | | |

AVERAGE INTENSITY = 10580.61

INTENSITY RANGE = 315.35

AVERAGE POLARIZATION = 47.16

POLARIZATION RANGE = 0.89

Introduction

These procedures should be performed once per month. Record all maintenance in the TD_x/TD_xFL_x® Maintenance Log.

Pipet Check

This test is used to check the instrument's ability to perform linear pipetting, independent of chemistries. The Pipet Check resets the MN TR (.21) for each assay.

To perform this test, you need:

An Assay Carousel
20 X SYSTEMS™ Sample Cartridges and Cuvettes
Pipet Check Solution (LN9531-02)
Pipet with Tips or Disposable Pipet

1. Place 20 sample cartridges and cuvettes into an assay carousel.
2. Invert the pipet check solution two to three times to ensure mixing.
3. Pipette a minimum of 75 µL of pipet check solution into each sample well.
4. Lock the carousel and place into the instrument and close the access door.
5. Press **TEST 2.3 RUN**. The display reads:

PIPE CHECK

6. The test will be completed in approximately fifteen (15) minutes. At the completion of a Pipet Check, if all values are correct, the intensity settings are stored. **DO NOT** press **STOP**, open the access door, or otherwise interrupt the check until the display returns to [READY]. An example of a typical Pipet Check printout is shown.
7. Ratios 1, 2, and 3 should be between 0.95 and 1.05. The AVG I (average intensity) of Group 16 through 20 must be greater than 4,000 and less than 10,000.

If the average intensity of Group 16 - 20 is less than 4,000, the error message **AVG I TOO SMALL** prints. If the value is greater than 10,000, the message **AVG I TOO LARGE** prints. If the range I value is greater than or equal to 250.00 for any group, **FAILED - RNG I OUT OF SPEC** prints.

If any ratio value is not within a range of 0.95 to 1.05, **ERROR** prints next to the ratio.

8. If values are out of specification, wash the probe and repeat Pipet Check. If values are still out of specifications, refer to Pipet Check Out of Specification in Section VI, Troubleshooting, under Observed Problems.

| PIPE CHECK | | | | | |
|-----------------|-------|-------|--------|---------|--|
| DATE: | | | | | |
| TIME: | | | | | |
| SERIAL #: | | | | | |
| REV. 1 | | | | | |
| LOC | H | V | I | P | |
| 1 | 30.9 | 45.1 | 107.0 | 186.4 | |
| 2 | 30.5 | 44.2 | 105.3 | 183.8 | |
| 3 | 31.8 | 45.1 | 108.7 | 173.2 | |
| 4 | 33.5 | 47.7 | 114.7 | 174.5 | |
| etc. | | | | | |
| REV 2 | | | | | |
| LOC | H | V | I | P | |
| 1 | 816.6 | 837.6 | 2471.0 | 12.6 | |
| 2 | 848.5 | 869.9 | 2567.0 | 12.4 | |
| 3 | 837.7 | 857.9 | 2533.4 | 11.9 | |
| 4 | 846.3 | 867.4 | 2560.1 | 12.2 | |
| etc. | | | | | |
| GROUP | RNG P | AVG P | RNG I | AVG I | |
| 1-5 | 0.92 | 12.22 | 96.02 | 2527.5 | |
| 6-10 | 0.88 | 12.00 | 181.43 | 3825.7 | |
| 11-15 | 0.83 | 11.98 | 174.45 | 5184.9 | |
| 16-20 | 0.91 | 12.05 | 216.65 | 5841.38 | |
| RATIO #1 = 0.99 | | | | | |
| RATIO #2 = 0.98 | | | | | |
| RATIO #3 = 0.97 | | | | | |

Precision Dispenser Calibration

1. Using an analytical balance with an accuracy of ± 1 mg, dispense a 200 μ L aliquot of distilled water into a small beaker and record its weight (W). Continue to dispense and record a total of 10 weights.
2. Reduce data by subtracting each recording from the subsequent recording ($W_i - W_{i-1} = W$ of aliquot) to obtain each individual aliquot weight.
3. Calculate mean (\bar{x}), standard deviation (SD), and % coefficient of variation (CV).

$$(\text{SD} \div \bar{x}) \times 100 = \% \text{ CV.}$$

Calibration is verified if $\bar{x} = 200 \pm 2$ mg and $\text{CV} \leq 2.0\%$.

If dispenser calibration is not within limits, repeat the calibration procedure. If dispenser fails again, contact the Customer Support Center.

Temperature Check

This test checks the operation of all temperature-control circuitry by measuring the temperature of cuvettes (with and without liquid), air, optics, and liquid heat block temperatures.

1. Place 20 empty cuvettes into an assay carousel.
2. Lock the cuvettes into place.
3. Place the loaded carousel into the instrument and close the access door.
4. Press **TEST 2.1 RUN**. The display reads:

TEMP CHECK

5. When the test is completed (approximately 15 minutes) [**READY**] displays.

NOTE: The operator may interrupt Temperature Check (by pressing **STOP**), after **IR COLD AND QUIET** and **IR COLD AND NOISY** print out. The remaining results, **V/F/D**, **CUVETTE TMPS BEFORE HEATING**, **WATCH FOR HEAT LEAKS**, and **AIR OPTICS LIQBLK VDET** are for factory and service use only.

EXPECTED RESULTS

TEMP CHECK

DATE:

TIME:

SERIAL #

CUVETTES WARM AND EMPTY –

| LOC | DEGREE C | TDET* |
|-----|----------|-------|
| 1 | 37.5 | 40.1 |
| 2 | 36.6 | 40.0 |
| 3 | 36.0 | 40.1 |
| 4 | 35.8 | 40.0 |

CUVETTES WARM AND EMPTY – TDET* between 39.7°C and 40.7°C.

SQUIRTING LIQUID

| LOC | LIQ BLK |
|-----------|-----------|
| 1 | 34.7 |
| 2 | 34.6 |
| 3 | 34.6 |
| 4 | 34.9 |
| H = 34.9* | L = 34.6* |

SQUIRTING LIQUID – H* and L* between 34.5°C and 35.5°C.

CUVETTE TMPS

| | WITH LIQ | W/O LIQ |
|---|----------|---------|
| 1 | 33.9 | 37.5 |
| 2 | 34.0 | 36.6 |
| 3 | 33.9 | 36.0 |
| 4 | 34.2 | 35.8 |

MEDIAN = 33.9*

RANGE = 0.3**

H = 34.1

L = 33.8

CUVETTE TMPS WITH LIQ MEDIAN* between 33.5°C and 34.5°C, RANGE** less than or equal to 1.5.

V/F/D CHECK

GND MEDIAN = 2.3597

H = 2.3597

RANGE = 0.0000

L = 2.3597

5V MEDIAN = 4.7267

H = 4.7267

RANGE = 0.0000

L = 4.7267

V/F/D CHECK – For factory use only.

IR COLD AND QUIET

(1) IR GND MEDIAN =
H =
RANGE =
L =

(2) IR DRK MEDIAN =
H =
RANGE =
L =

IR COLD AND NOISY

(3) IR GND MEDIAN =
H =
RANGE =
L =

(4) IR DRK MEDIAN =
H =
RANGE =
L =

IR COLD AND QUIET,
IR COLD AND NOISY,
IR GND Medians, and
IR DRK Medians should satisfy the following equations:

$$\frac{\text{MEDIAN (1)} - \text{MEDIAN (3)}}{\text{MEDIAN (1)}} \leq |0.005|$$

$$\frac{\text{MEDIAN (2)} - \text{MEDIAN (4)}}{\text{MEDIAN (2)}} \leq |0.005|$$

Diluent Syringe Wash

1. Refer to Component Replacement for instructions on diluent syringe removal and replacement.
2. Remove the diluent syringe from the TD_x analyzer, and pull the plunger out.
3. Wipe the white tip with a lint-free tissue moistened with distilled water.
4. Place a finger over the LUER LOK[®] end of the syringe, and fill the barrel with distilled water to rinse the syringe interior. Repeat this several times.
5. Reassemble and reinstall the syringe.

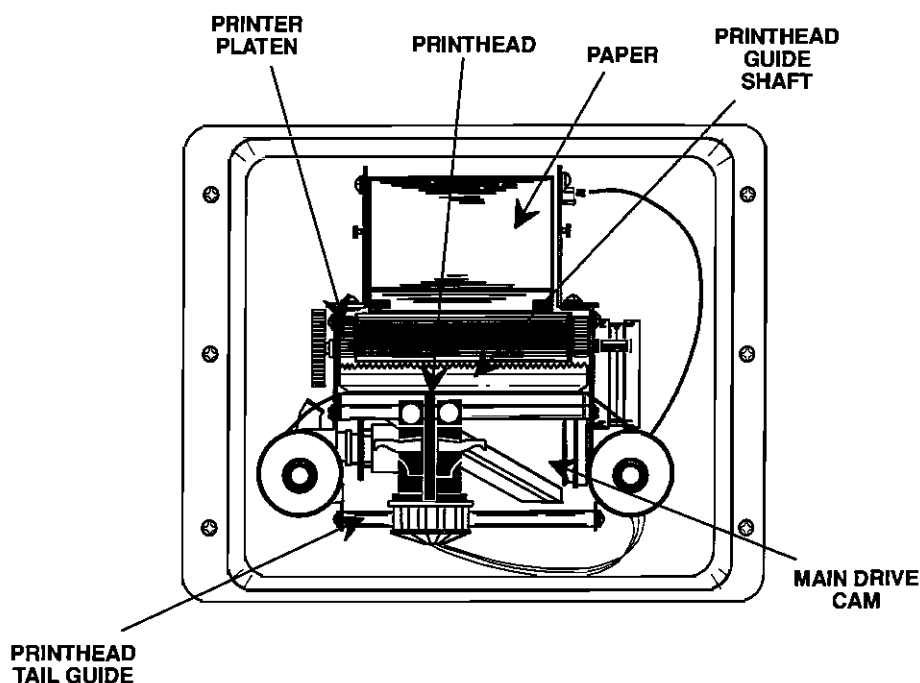
Printer (cleaning/ lubrication)

Cleaning

1. Wipe the printhead guide shaft with a clean cloth dampened with isopropanol.
2. Clean the old lubricant from the slot in the main drive cam and from the slot in the printhead tail guide with a cotton swab dampened with isopropanol. Move the printhead to clean both slots completely.

CAUTION: TO EXPOSE THE UNDERSIDE OF THE CAM, ROTATE THE CAM TOWARD THE PLATEN TO AVOID DAMAGE.

3. Rotate the printer platen by moving it toward the rear of the printer.
4. Clean the platen with a cloth dampened with isopropanol.



TD_x Printer

Lubrication

1. Apply a light coating of lubricant to the printhead guide shaft, the main drive cam slot, and the slot in printhead tail guide.
2. To distribute lubricant, press **TEST 5.4.1 RUN**.

**TD_x Centrifuge
Speed Check**

NOTE: For X SYSTEMS™ Centrifuge procedures, refer to the X SYSTEMS Centrifuge Instruction Guide.

Check the speed of the TD_x Centrifuge quarterly using the Centrifuge Speed Check procedure.

Equipment Needed

1. Calibrated photoelectric centrifuge tachometer
 - Abbott recommends the Shimpo DT-205 tachometer marketed by Shimpo America Corp., 3500 Devon Ave., Lincolnwood, IL 60659.
 - Although the Shimpo tachometer is recommended, any optical unit which provides consistent readings may be used. The instructions provided with the tachometer should be followed in taking measurements.
 - Do not use a tachometer which requires physically touching the rotating centrifuge head.
2. 20 centrifuge tubes

Use only X SYSTEMS™ Centrifuge Tubes (LN 9527-40).
3. Reflective tape

Reflective tape is supplied with tachometer or purchased from the tachometer distributor.

Procedure

1. Fill 20 centrifuge tubes with 1.5 mL water.
2. Snap the caps on securely and load the 20 centrifuge tubes into the centrifuge head.
3. Place the reflective tape on an area of the centrifuge head where it is easily detected by the tachometer and an accurate indicator of the RPM.
4. Close the lid.
5. Turn the time control dial to the 5 minute position and press the start button.

NOTE: The lid latch locks, the run indicator lamp illuminates and the centrifuge starts spinning.

6. Let the centrifuge run for 30 seconds before checking the speed with the tachometer.

7. Aim the light beam of the tachometer directly through the smoky plastic lid to take readings. Follow the instructions supplied with the tachometer.

8. Read the centrifuge operating speed in RPM.

Check Passes: RPM between 10,600 and 14,000

Check Fails: RPM outside of above range

9. If the centrifuge fails the Centrifuge Speed Check, the centrifuge must be calibrated using the Centrifuge Speed Calibration procedure in this section of the manual.

NOTE: Adjustments to the centrifuge speed may be required to compensate for motor brush wear, motor aging, or line-voltage fluctuation between locations or the installation of new operating components.

10. Turn the time control dial to zero.

TD_x Centrifuge Speed Calibration

NOTE: For X SYSTEMS™ Centrifuge procedures, refer to the X SYSTEMS Centrifuge Instruction Guide.

Centrifuge Speed Adjustment

If it is necessary to adjust the centrifuge speed, locate the potentiometer on either the back or side panel of the centrifuge.

Equipment Needed

1. Calibrated photoelectric centrifuge tachometer

Refer to the Centrifuge Speed Check procedure for the tachometer recommended by Abbott Laboratories.

2. 20 centrifuge tubes

Use only X SYSTEMS™ Centrifuge Tubes (LN 9527-40).

3. Thin-blade screwdriver or potentiometer trimming tool

4. Reflective tape

Reflective tape is supplied with the tachometer or purchased from the tachometer distributor.

Procedure

1. Fill 20 centrifuge tubes with 1.5 mL water.
2. Snap the caps on securely and load the 20 centrifuge tubes into the centrifuge head.
3. Place the reflective tape on an area of the centrifuge head where it is easily detected by the tachometer and an accurate indicator of the RPM.
4. Close the lid.
5. Turn the time control dial to the 5 minute position and press the start button.

NOTE: The lid latch locks, the run indicator lamp illuminates and the centrifuge starts spinning.

6. Let the centrifuge run for 30 seconds before checking the speed with the tachometer.
7. Aim the light beam of the tachometer directly through the smoky plastic lid to take readings. Follow the instructions supplied with the tachometer.
8. Read the centrifuge operating speed in RPM.
9. Insert a small screwdriver into the potentiometer.

Back Panel Potentiometer

Those units with speed adjustments on the back panel. There are two nuts on the shaft of the potentiometer. The inner nut mounts the potentiometer to the panel and **SHOULD NEVER BE LOOSENED**. The outer nut serves as a locknut for the shaft.

1. To adjust the potentiometer, loosen the outer nut and turn the shaft with a small screwdriver. Clockwise adjustment increases the speed. Counterclockwise adjustment decreases the speed.
2. Using the tachometer, continue to measure the RPMs and make adjustments with the potentiometer until the speed reads between 10,600 and 14,000 RPM.
3. Tighten the outer nut, and turn the time control dial to zero.

Side Panel Potentiometer

Side access potentiometer adjustments.

1. Using a small screwdriver or flat edged tool, remove the black button plug on the lower left side panel of the centrifuge and set aside.
2. Insert a thin screwdriver and turn. Clockwise adjustment decreases the speed, and counterclockwise adjustment increases the speed.
3. Using the tachometer, continue to measure the RPMs and make adjustments with the potentiometer until the speed reads between 10,600 and 14,000 RPM.
4. Turn the time control dial to zero and replace the access plug.

Barcode Reader Cleaning

1. Moisten cotton swab with distilled water and blot to remove excess water.
2. Gently wipe the lens on the underside of barcode reader to remove dirt or dried buffer. Dry the barcode reader with another swab.
3. Repeat cleaning if necessary.

Carousel Home Sensor Cleaning

1. Locate the carousel home sensor mounted in the baseplate at the 9 o'clock position.
2. Blow forced air (canned air, tubing from a laboratory air outlet, etc.) into the sensor to dislodge the dirt and lint particles.

TD_x Centrifuge Cleaning and Decontamination

NOTE: For X SYSTEMS™ Centrifuge procedures, refer to the X SYSTEMS Centrifuge Instruction Guide.

To properly maintain the centrifuge, use the following procedures and clean on an as needed basis:

The cleaning procedure requires removal of the centrifuge head.

Removing the centrifuge head from the centrifuge

1. **Unplug** the centrifuge from the AC outlet.
2. Loosen the thumbscrew that holds the head in place by turning it counterclockwise for several rotations.
3. Grip the center portion of the head and gently pull upward.

NOTE: This may take several attempts before the head is released.

4. After the head is released from the drive shaft, perform the cleaning procedure.

NOTE: If the head does not lift up, follow the procedure below for removing the centrifuge cover to provide additional leverage in removing the centrifuge head.

Removing the centrifuge cover

1. Remove the eight screws that hold the top cover on the unit. There are four screws on the top and two screws on each side.
2. Save the four washers that go on the sides of the cover.
3. Lift the cover straight up, and set aside.
4. Use both hands to reach under the rim of the head. Press down on the thumbscrew while pulling up on the rim. This procedure should provide enough leverage to remove the head.
5. After the head is released from the drive shaft, perform the cleaning procedure.

NOTE: If the centrifuge head cannot be removed, contact the Customer Support Center.

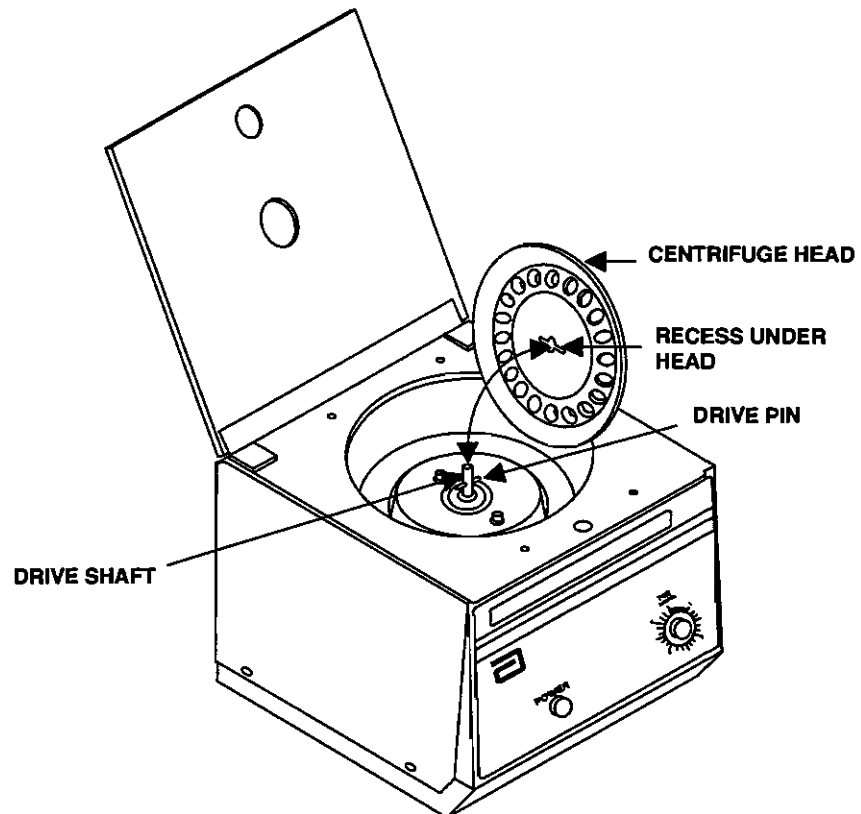
Cleaning the centrifuge and the centrifuge head

WARNING: • CONSIDER ALL CLINICAL SPECIMENS AND REAGENT CONTROLS, CALIBRATORS, ETC. THAT CONTAIN HUMAN BLOOD OR SERUM AS POTENTIALLY INFECTIOUS. WEAR GLOVES, LAB COATS, AND SAFETY GLASSES, AND FOLLOW OTHER BIOSAFETY PRACTICES AS SPECIFIED IN THE OSHA BLOODBORNE PATHOGEN RULE OR OTHER EQUIVALENT BIOSAFETY PROCEDURES.

CAUTION: • AVOID USING EXCESSIVE AMOUNTS OF WATER WHILE CLEANING. THIS MAY CAUSE DAMAGE FROM WATER SEEPAGE AROUND THE MOTOR SHAFT.

• AVOID THE USE OF ABRASIVE CLEANERS WHICH COULD SCRATCH THE SURFACES.

1. Clean using a damp cloth for the centrifuge and a damp swab for the centrifuge head.
2. Use a dry cloth for the centrifuge and a dry swab for the centrifuge head to remove all moisture.
3. Decontaminate using a 1% sodium hypochlorite (20% household bleach) solution.

Reinstalling the centrifuge head**CENTRIFUGE HEAD AND DRIVE SHAFT ALIGNMENT**

1. Locate the drive pin on the drive shaft and the recess under the centrifuge head.
2. Line up the pin and the recess so that they are perpendicular to each other.
3. Place the head on the shaft, and gently spin the head. The head should drop into correct alignment with the drive pin.

CAUTION: IMPROPER MOUNTING OF THE HEAD MAY CAUSE DAMAGE TO BOTH THE HEAD AND THE CENTRIFUGE. BE SURE THE ABOVE STEPS ARE FOLLOWED CORRECTLY.

4. Fasten the thumbscrew finger-tight and spin the head again.

NOTES: • Do not use a wrench or any other tool to tighten this screw.

- The head is installed correctly if it does not wobble.

5. Reinstall the top cover, screws, and washers if previously removed.

CAUTION: DO NOT RUN THE CENTRIFUGE UNTIL THE TOP COVER IS SECURED AND CLOSED.

6. Plug in the centrifuge.

Circuit Board Cleaning

To clean the contacts on a Printed Circuit Board (PCB):

1. Refer to Component Replacement in this section for the Circuit Board Removal Procedure.
2. Moisten a lint-free tissue with methanol and wipe the metal contacts on the edge of the PCB.

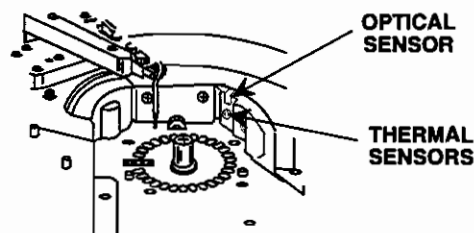
NOTE: DO NOT use alcohol preps.

3. Allow the methanol to evaporate.
4. Refer to Component Replacement in this section for the Circuit Board Replacement procedure.

Optical or Thermal Sensor Cleaning

To clean the optical or thermal sensor:

1. Moisten cotton swab with distilled water and blot the swab to remove excess water.
2. Locate the optical and thermal sensors as indicated below.
3. Gently clean the sensors with the moist cotton swab.
4. Visually inspect optical sensor and thermal sensor for cleanliness. Repeat cleaning as necessary.



Probe Decontamination Procedure

This procedure decontaminates the probe: The 1% sodium hypochlorite solution has been shown to inactivate infectious agents such as HIV and Hepatitis B.*

1. Press **SYSTEM 3.5 DISPLY**. Note the displayed value and press **STOP**.
2. Fill an empty cuvette to the top with 1% sodium hypochlorite and place the cuvette in position 1 of a batch assay carousel. Place the carousel in the instrument.
3. Press **TEST 4.1 RUN**.
4. Press **0, 7, 1**.
5. Press **NEXT** three times.
6. Press **0**.
7. Press **7**.
8. Press **4** six times.
9. Press **7**.
10. Press **4** to increase the step number or Press **1** to decrease the step number until the System 3.5 value noted in step 1 is displayed.
11. Press **9**.
12. Press **6** five times. The probe should now be immersed in the 1% sodium hypochlorite solution.
13. Press **CLEAR**.
14. Press **9**.
15. Press **6** thirty times (to draw the sodium hypochlorite solution into the probe). Let the probe soak for 15 minutes.
16. Press **EDIT** to dispense the sodium hypochlorite solution back into the cuvette and draw the solution back into the probe.
17. Press **STORE**.
18. Press **NEXT 9 STORE 7, 0 STOP**.
19. Press **PRIME** three times.
20. Remove the carousel and discard the cuvette.
21. Wash the probe with distilled water as described under Probe Wash in this section.

* Martin LS, McDougal JS, Loskoski SL. Disinfection and inactivation of the human T Lymphotropic Virus Type III/Lymphadenopathy-Associated virus. *J Infectious Diseases* August 1985; 152(2): 400-3.

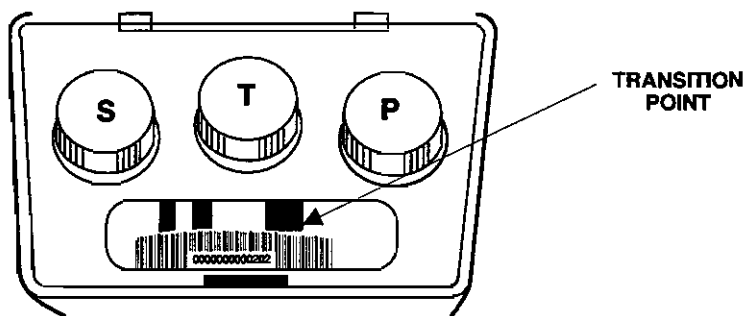
**Barcode Reader
Lateral Adjustment
Check**

This procedure describes how to adjust the lateral positioning of the barcode reader. There are two different labels read by the barcode reader, the reagent pack label (either 3-pot or 4-pot) and the carousel label. The procedure describes adjustment procedure for each label type.

Reagent Pack

1. Remove the vial caps and place a reagent pack into the instrument.
2. Print the System 3 parameters by pressing **SYSTEM 3 PRINT**.
3. Press **TEST 4.4 RUN**.
4. Press **SYSTEM**. The barcode reader is turned on and the barcode scans the reagent pack label. The display reads [BAR AMPL] followed by a number and alternates with the name of the reagent pack. If the assay name is being read correctly, go to the procedure for the Carousel Label. If the assay name is not being read correctly, proceed as follows:
 - a. Record the BAR AMPL value.
 - b. Press **0** to move the R-boom home.
 - c. Read five or six other reagent packs, with the vial caps removed, by pressing **SYSTEM**.
 - d. Proceed with the applicable steps below depending on the results observed with the reagent packs.
5. If the BAR AMPL reading is 20 or greater and the problem is isolated to one reagent system, display the MN TR for the assay by pressing **ASSAY XX.21 DISPLY**. If the MN TR equals zero, press **STOP** and activate that assay using System 5. If the activation code is not known, call the Customer Support Center.
6. If the BAR AMPL reading is less than 20, call the Customer Support Center.

7. If the BAR AMPL reading is greater than 20 and the assay name is read incorrectly, find the white to black transition point on the reagent pack barcode by performing the following steps:
 - a. Ensure that the barcode reader is turned on (red dots showing). If not on, press **SYSTEM** to turn it on.
 - b. Press and hold **1** to move the barcode reader to the left until the red dots appear to the left of the transition point as shown below. Press **4** to move the barcode reader to the right one step at a time until [R = B] appears in the display and the reader shines on the transition point of the barcode.
 - c. System parameter 3.10 and 3.11 should be 4 to 9 steps less than the step number (S=) showing at the exact point when the display reads [R = B].



8. If System 3.10 and 3.11 are not 4 to 9 steps less than the (S=) showing the transition point from white to black, edit as necessary by performing the following steps:
 - a. Press **STOP**.
 - b. Press **SYSTEM 3.10 EDIT** (enter a value that is seven steps less than the step number that was noted in the display) **STORE NEXT** (enter the same step number) **STORE STOP**.
9. Check for proper operation of the barcode reader by repeating steps 1 through 4 for several reagent packs.
10. If an occasional reagent label is reading incorrectly, press down firmly across the label, clean by wiping with lint free towel, and reread.

If the majority of the reagent labels are still reading incorrectly, call the Customer Support Center.
11. Return the boom arm home by pressing **0** then press **STOP** to return the instrument to [READY].

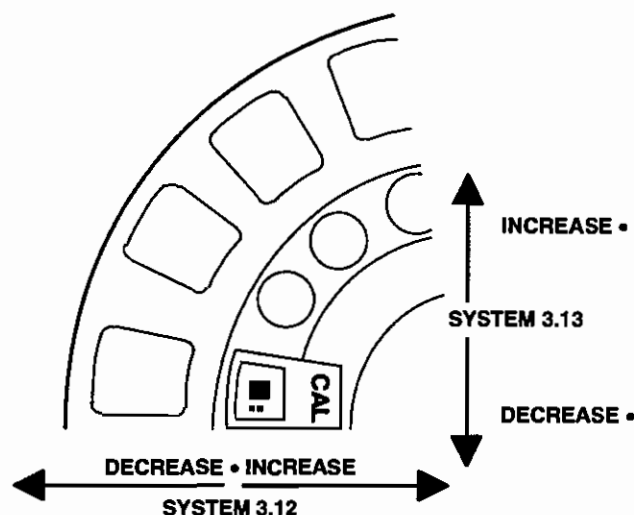
Carousel Label

1. Place a calibration carousel into the instrument. (Place a reagent pack with the vial caps removed into the TD_x System if this has not already been done.)
2. Press **SYSTEM 3 PRINT** to print System 3 parameters.
3. Press **TEST 4.1 RUN**.
4. Press **9 PRIME**. The barcode reader scans the carousel label. The display reads [BAR AMPL] followed by a number and alternate with the number on the carousel label.
 - a. The calibration carousel label number is 14.
 - b. The Fluorometric Standards Function Test Set Carousel label number is 13.
 - c. Assay carousels have specific numbers as labeled, and the analyzer displays this number.
 - d. The unit dose calibration carousel label number is 15.
 - e. The unit dose assay carousel label number is 16.

If the carousel label is read correctly and the BAR AMPL is 20 or greater, press **STORE STOP** to return the instrument boom arm home and the instrument to [READY]. If the carousel number is not read correctly, proceed as follows:

- a. Record the BAR AMPL value.
 - b. Press **STORE** to move the boom arm home.
 - c. Place an assay carousel into the instrument, and read the label by pressing **PRIME**.
 - d. Proceed with the applicable steps below depending on the results observed with the carousels.
5. If the problem occurs with only one carousel, put a new label on that carousel.

6. If the BAR AMPL reading is less than 20 on the carousel or greater than 20 on the reagent pack label and the carousel is being read incorrectly, proceed as follows with the calibration carousel in the instrument:
 - a. Press **STORE** to home the R-boom.
 - b. Place the calibration carousel into the instrument.
 - c. Press **7, 0** to home the carousel.
 - d. Press **7** until [TB = 2] appears in the display, then press **1** repeatedly until [TB = 20] appears in the display.
 - e. Press **7** then **1** or **4** until (S=) shows the same step number as System 3.13.
 - f. Press **9** then **EDIT** to turn the barcode reader on.
 - g. After the reagent pack label is scanned, press **STORE** to home the boom.
 - h. Press **9** until [TB = 1] appears in the display.
 - i. Press **6** until the barcode reader is near the carousel.
 - j. Press **9** until (S=) appears in the display then press **6** or **3** as needed until (S=) shows the same step number as System 3.12.
7. The red dots should be clearly visible in front of the barcode as shown below and should be approximately centered left to right. (The barcode reader dots may not be in the same horizontal orientation as shown.)



If the red dots are not centered, press **6** to move the reader to the right or **3** to move the reader to the left until the dots are centered. Record the step number (S=) showing in the display. At the completion of this procedure, System 3.12 should equal this value plus or minus two steps. If it does not, edit System 3.12 to the correct value by performing step 8.

To find the step number where the barcode reader detects the transition from white to black on the barcode label, proceed as follows:

- a. Press **7** twice until (S=) appears in the display.
 - b. Press **4** once to move the carousel counterclockwise one step.
 - c. Press **9** and note whether (R=B). If (R=W), press **7**, **4** and **9** in sequence until (R=B).
 - d. When (R=B), press **7**.
 - e. System parameter 3.13 should be 4 to 9 steps less than the step number (S=) showing when (R=B) showed in the display. If it is not, edit System 3.13 to the correct value by performing step 8.
8. To edit System 3.12 or 3.13 parameters perform the following steps:
- a. Press **STOP SYSTM 3.XX EDIT** (enter the step number)
STORE STOP.
9. If an adjustment has been made, check for proper operation of the barcode reader by repeating steps 3 and 4 for all carousels.
10. Press **STORE STOP** to return the boom arm home and return the instrument to [READY]. It is not necessary to perform any calibration procedures.

Boom Calibration Verification

This procedure verifies that System 3 parameters for probe position are correct.

If desired, a Boom Calibration (Test 3.2) can be run to set the System 3 probe and barcode reader positions. If applicable, also run a 4-Pot Reagent Pack Boom Calibration (Test 3.7). Refer to Section IV, Diagnostic Checks, under Diagnostic Tests, for these procedures.

To perform this check, you need the following items:

3-Pot Reagent Pack
Carousel
1 Sample Cartridge
1 Cuvette

1. Open a reagent pack, remove the caps, and place into the instrument.
2. Place a sample cartridge and cuvette into position 1 of the carousel. Place carousel on the centerpost.
3. Press **SYSTM 3 PRINT**.
4. Press **TEST 4.1 RUN**.
5. Press **0** to home the carousel.
6. Press **7** until [TB = 2] is displayed.
7. Press **1** once to position sample #1 in sampling position and [TB = 1] is displayed.
8. Press **NEXT** three times.
9. Press **0** to home R-boom.

10. Verify that the probe is properly positioned for System 3 parameters 3.3 through 3.9 as follows:
 - a. Press **4** until S= SYSTEM 3.6 from the printout obtained in step 3.
 - b. If the probe is not centered over the "P" vial, center the probe by pressing key **1** or **4** as applicable.

If it is necessary to move the probe down to assist in verifying probe position, do the following:

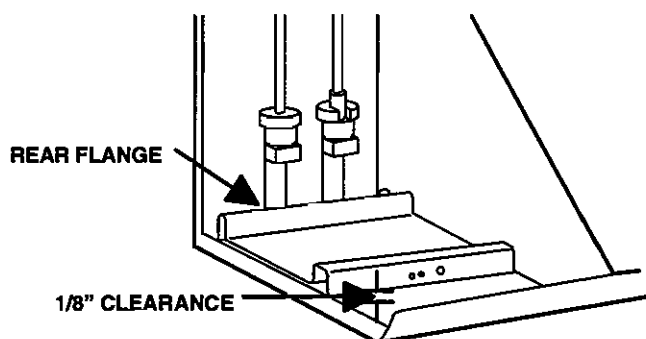
 - 1) Press **9** twice.
 - 2) Press **6** to move probe down or **3** to move probe up.
 - 3) Press **STORE** to home Z-boom.
 - 4) Press **7** twice to return to step 10.
 - c. Record the step number showing in display when probe is properly centered.
 - d. Repeat steps (a) through (c) for the following positions:

| | |
|--------------------|------------|
| - "T" vial | System 3.7 |
| - "S" vial | System 3.8 |
| - Waste opening | System 3.9 |
| - Sample well | System 3.3 |
| - Predilution well | System 3.4 |
| - Cuvette | System 3.5 |
11. Press **0** to return R-boom home.
12. Press **STOP** to return to [READY].
13. Enter step numbers recorded in step 10c for each parameter as follows:
 - a. Press **SYSTM 3.X EDIT**. (X represents the specific parameter being changed.)
 - b. Enter the new step number and press **STORE**.
 - c. Press **STOP** to return to [READY].

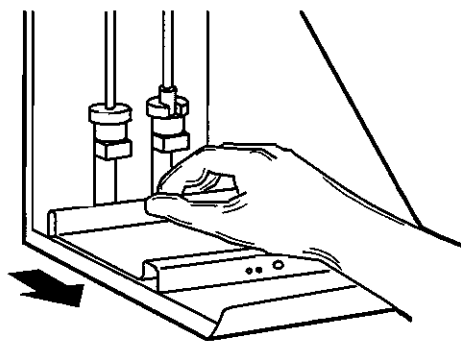
**Buffer Platform
Adjustment**

This procedure adjusts the buffer platform so the buffer sensor properly detects a buffer container with low volume.

1. Remove the buffer access door. Lift the buffer container off the platform and set it to the side of the instrument.
2. There should be approximately 1/8" clearance between the base of the TD_x analyzer and the lower front edge of the buffer platform as shown below.
3. To increase the clearance, push back on the rear flange of the buffer platform until there is approximately 1/8" clearance when the platform is released and comes to rest.



4. To decrease the clearance, pull forward on the rear flange of the buffer platform as shown below until there is approximately 1/8" clearance when the platform is released and comes to rest.



5. To verify the platform is properly positioned, place a buffer container with approximately 100 mL of buffer on the platform and press **TEST 4.3 RUN 9**. If the display reads [B=N], the platform is adjusted properly. The display should change to [B=Y] when buffer is added to the container. It is not necessary to perform any instrument calibration procedures.

**Liquid-Level-Sensing
Adjustment**

The purpose of this procedure is to check and set the Z-boom home position so a minimum volume (50 µL) of sample is detected properly.

NOTE: Diagnostic Test 3.5 (Z-boom CAL) may be used instead of this procedure to set the Z-boom home.

The following items are necessary:

Carousel
50 µL Pipettor
Five Sample Cartridges

1. Place sample cartridges in positions 1, 5, 10, 15 and 20 of a carousel.
2. Accurately pipette 50 µL of X SYSTEMS™ Dilution Buffer into each sample well. Pipette the buffer directly into the bottom of the sample well.
3. Place carousel into instrument. Press **SYSTEM 3 PRINT** to obtain System 3 parameters.
4. Press **TEST 4.1 RUN**.
5. Press **0** to home the carousel.
6. Press **7** until [TB = 2] is displayed.
7. Press **1** once to position sample #1 in sampling position.
[TB = 1] should display.
8. Press **NEXT** three times.
9. Press **0** to home the R-boom.
10. Press **7** until [TB = 1] displays.
11. Press **4** four times to move probe to the right near the sample well.
12. Press **7** until [S =] displays.
13. Press **1** or **4** as needed to center probe over sample well. (S) should equal System 3.3 parameter. If (S) does not equal the System 3.3 parameter, it may be necessary to adjust the parameter by noting the appropriate step number that is displayed (S=) when the probe is properly centered. Then, at the completion of this procedure, edit System 3.3 to the correct step number.
14. Press **9** twice.
15. Press **DISPLY** and note step number when [L = Y]. Record step number (S=) for this carousel position.

-
16. Verify proper liquid-level sensing (LLS) at other positions (5, 10, 15, and 20) as follows:
 - a. Press **STORE** to home Z-boom.
 - b. Press **CLEAR** three times.
 - c. Press **7** until (TB=) displays.
 - d. Press **4** until next sample cartridge is in sampling position (for example, TB=5, 10, 15, 20).
 - e. Press **NEXT** three times.
 - f. Press **9**.
 - g. Press **DISPLY** and note step number when [L = Y]. Record the step number for this carousel position.
 - h. Repeat steps a – g for each sample cartridge. When all step numbers are recorded, proceed to item 17.
 17. Press **STORE 7** and **0** to home Z and R booms.
 18. Press **STOP** to return to [READY].
 19. The LLS (where L=Y) step number for each position should be 172 or 173. If all step numbers meet this criteria, the probe height is properly adjusted. Proceed to item 21. If all step numbers do not meet this criteria, the Z-boom home step number must be adjusted as follows:
 - a. Determine the largest step number where [L = Y].
 - b. Display present Z-boom home (ZBM HM) position by pressing **SYSTEM 3.14 DISPLY** and record step number.
 - c. Calculate new ZBM HM position as follows:
 $[173 - \text{step \# in (a)}] + [\text{step \# in (b)}] = \text{new ZBM HM position.}$
 - d. Store new ZBM HM position by pressing **EDIT** (step # calculated in step c) **STORE**.
 - e. Press **STOP** to return to [READY].
 20. Repeat procedure starting with item 4 to ensure LLS occurs in all five sample cartridges at step number 172 or 173. (No location should read more than 173 or minimum fluid volume in the location will be skipped during a run.)
 21. At completion of procedure, remove carousel, discard contents and press **PRIME** twice.

Probe-Positioning Check and Adjustment (Batch)

To ensure the highest level of performance from the TD_x System it is extremely important that the probe be precisely positioned. The following is a step-by-step procedure to check and adjust the probe position in order to optimize system performance in the batch mode of operation.

To perform this procedure, the following equipment is necessary:

Sample Carousel

Batch Probe-Positioning Cartridge

1. Place the batch probe-positioning cartridge into location #1 of a sample carousel. Place the carousel into the instrument. Leave the access door open. Press **SYSTEM 3 PRINT**.
2. Use hand controls (steps A-N) to check the probe position in the predilution well:

| Step | Operator Action | System Response | Display |
|------|---|---|--|
| | | | (X= variable stepper numbers or home status) |
| A | Press TEST 4.1 RUN . | Activates test | HC=H or N C=X S=XXX |
| B | Press 0 . If HC=N, press STOP PRIME , and repeat steps A and B. If HC=H, continue to step C. | Moves the carousel to home | HC=H C=X S=XXX |
| C | Press 7 . | Changes to a tab function | HC=H C=X TB=2 |
| D | Press 1 . | Rotates the probe-positioning cartridge to the sampling station | HC=N C=X TB=1 |
| E | Press NEXT three times. | Changes to R-boom control | HR=X R=W S=X |
| F | Press 0 . | Moves the R-boom to home | HR=H R=W S=X |
| G | Press 7 . | Changes to a tab function | HR=H R=W TB=1 |
| H | Press 4 five times. | Moves the R-boom near the predilution well by tab increments | HR=N R=W TB=6 |
| I | Press 7 . | Changes to a step function | HR=N R=W S=XXX |
| J | Press 4 to move right, or press 1 to move left, until the step value [S=XXX] equals the System 3.4 parameter value obtained on the printout in step 1. If the probe appears to be in line with the opening in the predilution well, continue to step K. If not, press 4 or 1 until alignment is achieved. | Adjusts probe left or right by step increments | HR=N R=W S=XXX |

| Step | Operator Action | System Response | Display |
|------|---|---|----------------|
| K | Record the step [S=XXX] value. | N/A | HR=N R=W S=XXX |
| L | Press 9 . | Changes to Z-boom control | HZ=H L=X TB=X |
| M | Press 9 . | Changes to a step function | HZ=H L=X S=XX |
| N | Press 6 as necessary until the probe enters the opening in the predilution well. | Moves the probe down by step increments | HZ=N L=X S=XX |

3. If properly positioned, the probe tip should enter the opening in the probe-positioning cartridge to the most forward point without moving the cartridge. If the positioning is correct, return the boom home by pressing **STORE 7, 0** then **STOP**. Proceed to step 6.

If the probe is not properly positioned left to right, press **STORE 7** (twice) and return to step J. Edit the System 3.4 parameter to the value recorded in step K at the completion of any necessary front to back adjustments. Repeat steps L, M and N.

NOTE: The System 3.4 parameter can be edited when adjustments are complete by pressing **SYSTM 3.4 EDIT** (enter new **R-boom step number recorded in step K**) and **STORE**. Press **STOP** to return to [READY].

If the probe is not positioned properly front-to-back (the probe moves the cartridge or is positioned so it will not enter the opening), make the necessary front-to-back position adjustments as follows:

- Refer to the Access Door Removal and Replacement procedure in this section if you find it necessary to remove the access door in order to perform this procedure.

DANGER: THE INSTRUMENT MUST BE TURNED OFF AND UNPLUGGED FROM THE POWER SOURCE. DO NOT REMOVE DOOR WITH THE POWER TURNED ON.

- Supporting the underside of the boom to avoid damaging the probe tip, carefully loosen the two knurled thumbscrews on top of the boom arm $\frac{1}{8}$ to $\frac{1}{4}$ turn.
- Move the probe holder into or out of the boom arm as needed to position the probe in the forward portion of the probe positioning cartridge opening.
- Supporting the underside of the boom arm, holding the probe securely in place, tighten the two knurled thumbscrews to secure the probe.
- If the access door has been removed, replace the front panel only and secure with one front panel screw. Power the instrument ON. Enter the date and time. [READY] appears in the display. Press **PRIME** to home the Z-boom and R-boom.

4. To verify that the proper front-to-back probe alignment was obtained, repeat steps 2 A-N. If another adjustment is required, follow step 3, then verify positioning by performing steps 2 A-N again.
5. When the adjustment and subsequent verification is complete, press **STORE 7, 0** then **STOP**.
6. If the access door was removed, refer to the Access Door Removal and Replacement procedure in this section to reinstall the access door.

DANGER: DO NOT PLUG IN OR POWER ON THE TD_x ANALYZER WITH THE FRONT PANEL REMOVED.

7. Run a batch Boom Calibration (Test 3.2).
8. Run a 4-Pot Reagent Pack Boom Calibration (Test 3.7), if applicable.

Probe-Positioning Check and Adjustment (Unit Dose)

To ensure the highest level of performance from the TD_x System, it is extremely important that the probe be precisely positioned in the various cartridge wells, reagent wells, etc. This is especially true for the predilution well, the sample well, and, in the case of unit dose, the three foil covered reagent wells. The following is a step-by-step procedure to check and adjust the probe position in order to optimize system performance in both the batch and unit dose modes of operation.

NOTE: This procedure requires a unit dose probe-positioning cartridge.

1. Insert a unit dose probe-positioning cartridge into position #1 of a unit dose carousel and place the carousel into the instrument. Leave the access door open. Press **SYSTEM 3 PRINT** and **SYSTEM 8 PRINT**.
2. Use hand controls (steps A-N) to check the probe position in the predilution well:

| Step | Operator Action | System Response | Display |
|------|---|---|--|
| | | | (X= variable stepper numbers or home status) |
| A | Press TEST 4.1 RUN . | Activates test | HC=H or N C=X S=XXX |
| B | Press 0 . If HC=N, press STOP PRIME , and repeat steps A and B. If HC=H, continue to step C. | Moves the carousel to home | HC=H C=X S=XXX |
| C | Press 7 . | Changes to a tab function | HC=H C=X TB=2 |
| D | Press 1 . | Rotates the unit dose probe-positioning cartridge to the sampling station | HC=N C=X TB=1 |
| E | Press NEXT three times. | Changes to R-boom control | HR=X R=W S=X |
| F | Press 0 . | Moves the R-boom to home | HR=H R=W S=X |

| Step | Operator Action | System Response | Display |
|------|---|--|----------------|
| G | Press 7. | Changes to a tab function | HR=H R=W TB=1 |
| H | Press 4 five times. | Moves the R-boom near the predilution well by tab increments | HR=N R=W TB=6 |
| I | Press 7. | Changes to a step function | HR=N R=W S=XXX |
| J | Press 4 to move right, or press 1 to move left, until the step value [S=XXX] equals the System 3.4 parameter value obtained on the printout in step I. If the probe appears to be in line with the opening in the predilution well, continue to step K. If not, press 4 or 1 until alignment is achieved. | Adjusts probe left or right by step increments | HR=N R=W S=XXX |
| K | Record the step [S=XXX] value. | N/A | HR=N R=W S=XXX |
| L | Press 9. | Changes to Z-boom control | HZ=H L=N TB=1 |
| M | Press 9. | Changes to a step function | HZ=H L=N S=XX |
| N | Press 6 as necessary until the probe enters the opening in the predilution well. | Moves the probe down by step increments | HZ=N L=N S=XX |

3. If properly positioned, the probe tip should enter the opening in the unit dose probe-positioning cartridge to the most forward point without moving the cartridge. If the positioning is correct, return the boom home by pressing **STORE 7** then **0**. Proceed to step 6.

If the probe is not properly positioned left to right, press **STORE 7** (twice) and return to step J. Edit the System 3.4 parameter to the value recorded in step K at the completion of any necessary front to back adjustments. Repeat steps L, M and N.

NOTE: The System 3.4 parameter can be edited when adjustments are complete by pressing **SYSTM 3.4 EDIT** (enter new **R-boom step number recorded in step K**) and **STORE**. Press **STOP** to return to [READY].

If the probe is not positioned properly front-to-back (the probe moves the cartridge, or is positioned so it will not enter the opening), make the necessary front-to-back position adjustments as follows:

- a. Refer to Access Door Removal and Replacement procedure in this section if you find it necessary to remove the access door in order to perform this procedure.

DANGER: THE INSTRUMENT MUST BE TURNED OFF AND UNPLUGGED FROM THE POWER SOURCE. DO NOT REMOVE DOOR WITH THE POWER TURNED ON.

- b. Supporting the underside of the boom to avoid damaging the probe tip, carefully loosen the two knurled thumbscrews on top of the boom arm $1/8$ to $1/4$ turn.
 - c. Move the probe holder into or out of the boom arm as needed to position the probe in the forward portion of the unit dose probe-positioning cartridge opening.
 - d. Supporting the underside of the boom arm, holding the probe securely in place, tighten the two knurled thumbscrews to secure the probe.
 - e. If the access door has been removed, replace the front panel only and secure with one front panel screw. Power the instrument ON. Enter the date and time. [READY] appears in the display. Press **PRIME** to home the Z-boom and R-boom.
4. To verify that the proper front-to-back probe alignment was obtained, repeat steps 2 A-N. If another adjustment is required, follow step 3, then verify positioning by performing steps 2 A-N again.
 5. When the adjustment and subsequent verification is completed, press **STORE 7** then **0** to home the Z-boom and R-boom. Proceed to step 6.
 6. Perform steps O-T to check the probe positioning in the "T" well of the unit dose probe-positioning cartridge:

| Step | Operator Action | System Response | Display |
|------|---|--|--|
| | | | (X= variable stepper numbers or home status) |
| O | Press 7 as necessary to enter into a step function. | Changes to a step function | HR=H R=W S=XXX |
| P | Press 4 to move right, or press 1 to move left, until the step value [S=] in the display equals the System 8.4 parameter value obtained on the printout in step 1. If the probe appears to be in line with the opening in the "T" well, continue to step Q. If not, press 4 or 1 until alignment is achieved. | Adjusts probe left or right by step increments | HR=N R=W S=XXX |

| Step | Operator Action | System Response | Display |
|------|--|---|---------------|
| Q | Record the step [S=XXX] value. | | |
| R | Press 9. | Changes to Z-boom control | HZ=H L=N TB=1 |
| S | Press 9. | Changes to a step function | HZ=H L=N S=XX |
| T | Press 6 as necessary until the probe enters the opening in the "T" well. | Moves the probe down by step increments | HZ=N L=N S=XX |

7. If properly positioned, the probe tip should enter the opening in the "T" well of the unit dose probe-positioning cartridge without moving the cartridge.

If the positioning is correct, return the boom home by pressing **STORE 7, 0** then **STOP**. Proceed to step 8.

If the probe is not properly positioned left to right, press **STORE 7** (twice) and return to step P. Repeat steps P-T. The System 8.4 parameter should be edited to the value recorded in step Q.

NOTE: The System 8.4 parameter can be edited when adjustments are complete by pressing **SYSTM 8.4 EDIT** (enter the new R-boom step number recorded in step Q) and **STORE**. Press **STOP** to return to [READY].

If the probe hits in front or behind the opening, the positioning is not correct. Contact the Customer Support Center.

8. If the access door was removed, refer to the Access Door Removal and Replacement procedure in this section to reinstall the access door.

| |
|--|
| DANGER: DO NOT PLUG IN OR POWER ON THE TD _X ANALYZER WITH THE FRONT PANEL REMOVED. |
|--|

9. Run a batch Boom Calibration (Test 3.2).
10. Run a Unit Dose Boom Calibration (Test 3.6), if applicable.
11. Run a 4-Pot Reagent Pack Boom Calibration (Test 3.7), if applicable.

For any of the following procedures during which power to the TD_x System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.

Access Door Removal and Replacement

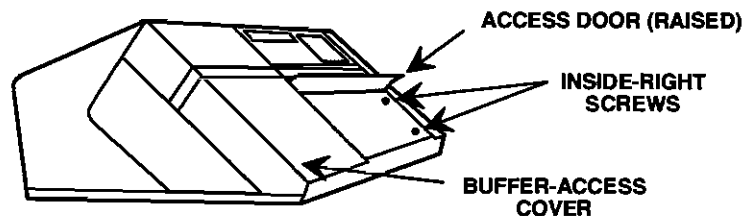
The following procedure describes how to remove and replace the front panel and access door to allow easy access to the TD_x analyzer interior. A phillips and a blade screwdriver are required for this procedure.

Removal

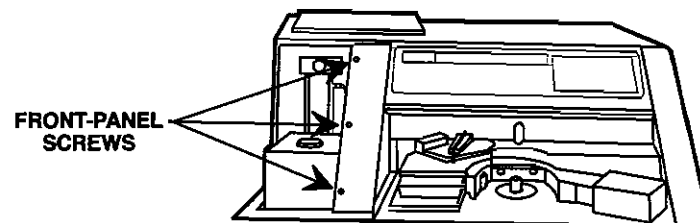
1. Turn power off and unplug the power cord from the wall outlet.

DANGER: DAMAGE MAY RESULT TO THE TD_x ANALYZER OR THE OPERATOR MAY BE HARMED IF THE TD_x ANALYZER IS NOT UNPLUGGED BEFORE PROCEEDING.

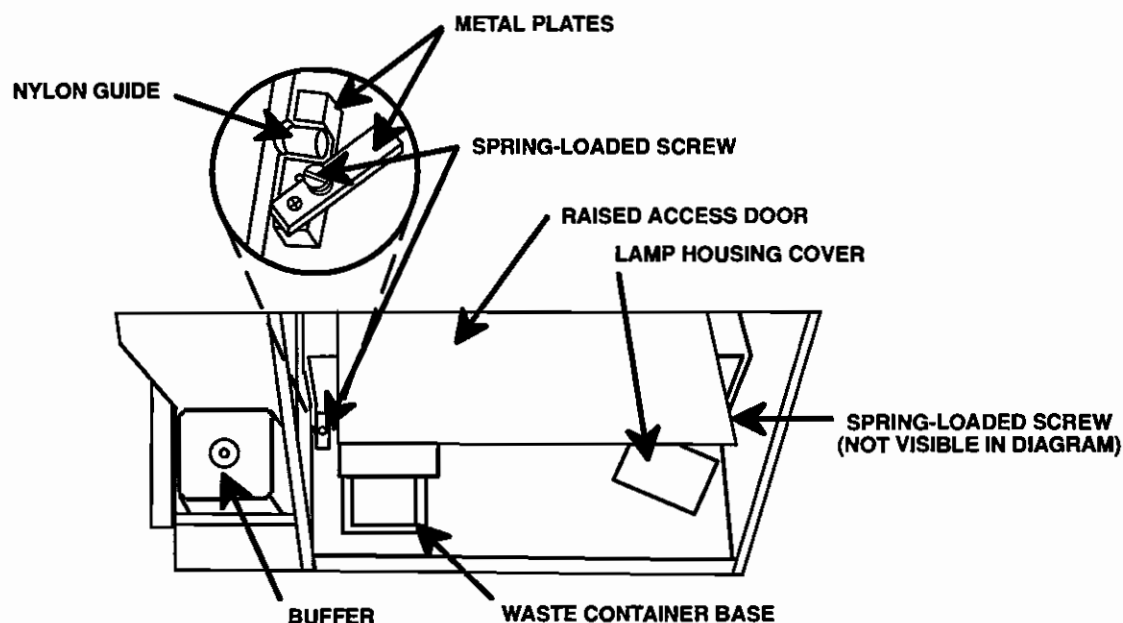
2. Raise the access door, and remove the inside-right screw(s) above the lamp housing.



3. Remove the lift-off buffer access cover.
4. Remove the three front-panel screws.



5. Lift the front panel up and lay it carefully face down on top of the instrument. It is not necessary to remove the ribbon cables connected to the front panel.
6. To remove the access door, loosen the two spring-loaded (blade) screws. (Do not loosen the phillips screws that secure the metal plate to the base of the TD_x analyzer). Using the screwdriver, move the metal plates toward the center of the instrument.



7. Disconnect the ground strap from the access door.
8. Carefully lift the access door straight up and out to remove it from the instrument. Place the access door flat on the counter.

CAUTION: ENSURE THAT NO CABLES OR TUBING ARE CAUGHT ON THE ACCESS DOOR AS IT IS REMOVED.

DO NOT PLUG IN OR POWER ON THE TD_x ANALYZER WITH FRONT PANEL REMOVED.

Replacement

1. Place the access door into the instrument so the two nylon guides, one on each side support, fit into the notch in the metal plate (see the access-door-removal diagram following step 6). Ensure that the interconnect tubing from the sample syringe is positioned behind the access door. The access door is properly installed when the angled side supports extend back toward the mother board. Ensure that the nylon guides are in the notches.
2. Move each metal plate over the nylon guides on the access door, and resecure the spring-loaded screws with a screwdriver. Leave the access door in the raised position. Reconnect the ground strap to the access door.

3. Replace the front panel onto the instrument ensuring that the ribbon cables do not protrude outside the top of the instrument.
 4. Reattach the three front-panel screws. Refer to the access-door-removal diagram following step 4.
 5. Reattach the inside right screws. Refer to the access-door-removal diagram following step 2. Attach the screws snugly but **do not** overtighten.
 6. Lower the access door.
 7. Plug the outlet back into the wall and turn the power on. Initialize the system by entering and storing the correct date and time.
-

Buffer Replacement

If there is insufficient buffer to complete an assay:

1. The display reads:

BUFFER EMPTY

Press **STOP**.

2. Remove the buffer access cover on the left of the instrument.
3. Twist off the buffer cap with attached tubing; remove and discard the empty buffer bottle. Be careful not to crimp the inlet tubing when removing the bottle. To avoid possible contamination, do not combine contents of different bottles.
4. Replace the cap and tubing on a full X SYSTEMS™ Dilution Buffer bottle and set into position. Check to verify that the waste container is in position, then press **PRIME**.
5. Prime five times to eliminate any trapped air bubbles. Refer to the procedure on air bubble removal if necessary, Section VI, Troubleshooting, under Observed Problems.
6. Replace the buffer access cover.

Circuit Board Removal and Replacement

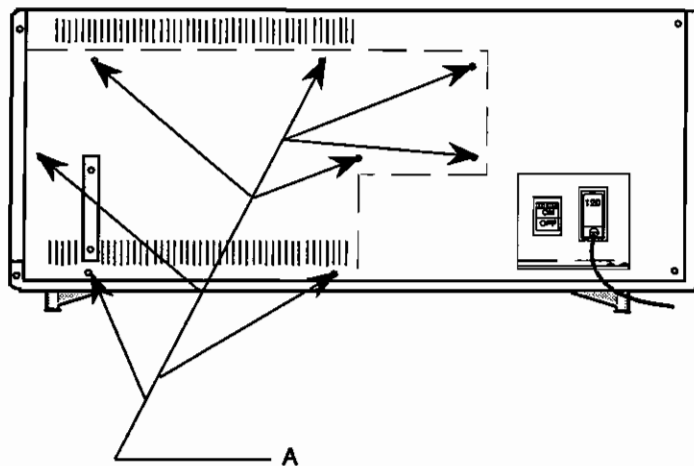
This procedure describes the steps necessary to remove, and replace a printed circuit board (PCB).

Removal

1. Turn TD_x System power off and unplug unit from wall outlet.

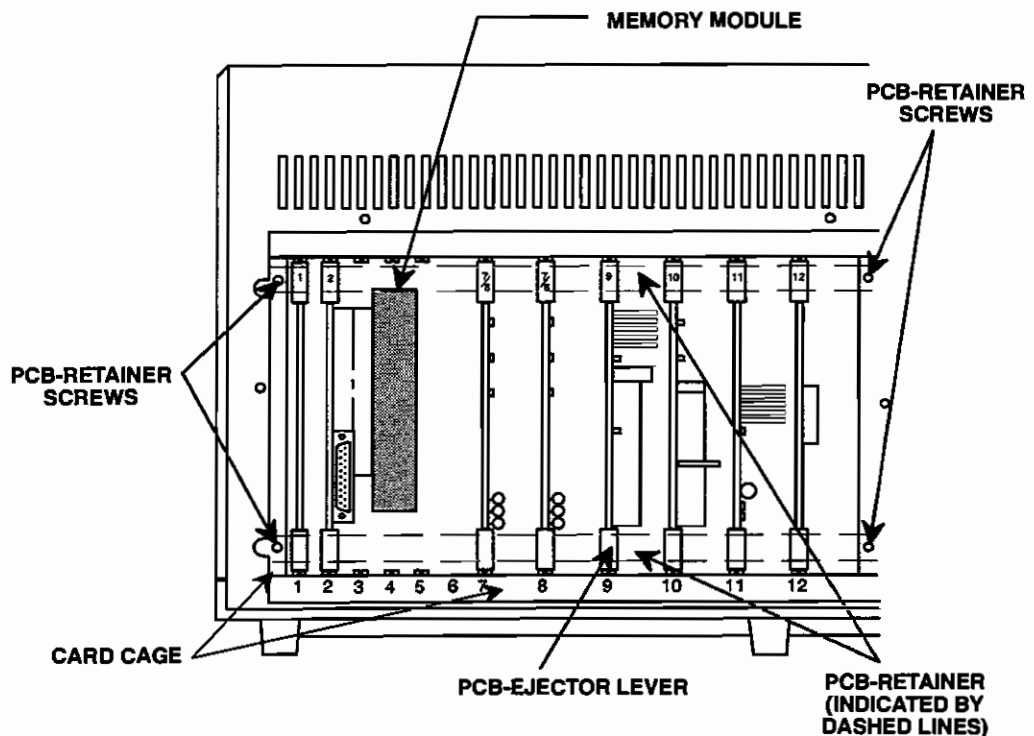
DANGER: ALWAYS HAVE POWER OFF AND UNIT UNPLUGGED WHEN REMOVING OR INSTALLING A PCB.

2. Remove the screws labeled (A). Some rear panels have six screws, others have eight.



3. Remove the rear panel to allow access to the card cage. PCB card slots are numbered from 1 to 12.

4. Determine if PCB retainer(s) (silver bars that attach to the card cage, over the PCB-ejector levers) are installed in the analyzer.
 - If **not present**, continue to step 5.
 - If **present**, remove them before continuing as follows:
 - a. Remove the PCB-retainer screws.
 - b. Remove the PCB-retainer(s).
 - c. Discard the PCB retainer and screws.



NOTES: Slots 3, 4, 5 and 6 are empty.

To remove Memory Module from PCB #2, remove PCB #2 from card cage. Loosen thumbscrews on the top of the memory module. Module can then be separated from the PC board.

When installing the memory module, ensure that the module is held securely by the retaining clip and that the thumbscrews are finger-tight.

The TD_x System does not power on if the rear panel is not reinstalled properly.

5. To remove a PCB, simultaneously lift up on the top lever and push down on the bottom lever. When the PCB has been loosened, pull it completely free of the card cage. To prevent an accidental mix-up, **do not** remove more than one PCB at a time. If only the reseating of a PCB is necessary, do not pull the board completely free of the card cage.

Replacement

1. To install, orient the PCB so the components are on the right side as the board is inserted into the card cage slot.
2. Insert the PCB into the correctly numbered slot. The number on the ejector lever should match the number on the card cage.
3. Ensure that the top and bottom edges of the PCB are in the guides.
4. To seat the PCB in the card cage connector, simultaneously press firmly on the top and bottom levers until a distinct click can be heard.
5. Replace the rear panel, and reattach the screws. No instrument calibration is required after performing this procedure.

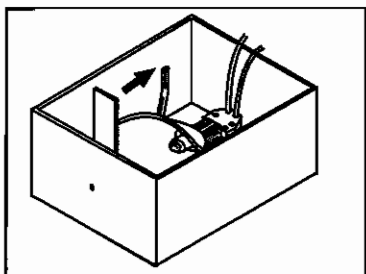
Lamp Replacement

To replace the lamp, use the procedure listed below.

CAUTION: USE THE DESIGNATED LAMP (LN 9520-12) AS ORDERED FROM ABBOTT LABORATORIES. USE OF ANY OTHER LAMP MAY ADVERSELY AFFECT ASSAY RESULTS.

1. Open the access door and remove the lamp cover. Note how the lamp is positioned in the lamp housing.
2. Push the lamp ejector bar to the right and lift the lamp out of the housing.

CAUTION: THE LAMP MAY BE VERY HOT.



3. Unplug the lamp from the lamp holder.
4. Inspect the contacts on the new lamp. Clean with emory cloth or sandpaper if there is evidence of corrosion.
5. Using a lint-free cloth, grasp the new lamp by the small inner bulb and insert the prongs into the socket.

NOTE: The base of the lamp is made of ceramic that can crack if pressure is applied improperly. By holding the inner bulb firmly, the possibility of cracking the ceramic is minimized.

6. Seat the lamp down firmly in the lamp housing. Ensure that the lamp ejector bar returns to the left and that the face of the lamp is parallel to the lamp housing wall.
7. Place the connecting wires through the notch on the right side of the lamp housing.
8. To check the operation of the lamp, press **TEST 4.2 RUN PRIME**. The source lamp should light. Press **STOP** to return to [READY]. If lamp does not light, replace with another new lamp assuring that the contacts are clean and the filament is not broken (steps 2-8).
9. Replace the lamp cover securely on the lamp housing to prevent stray light.

**Printer Paper/Ribbon
Replacement**Paper Replacement

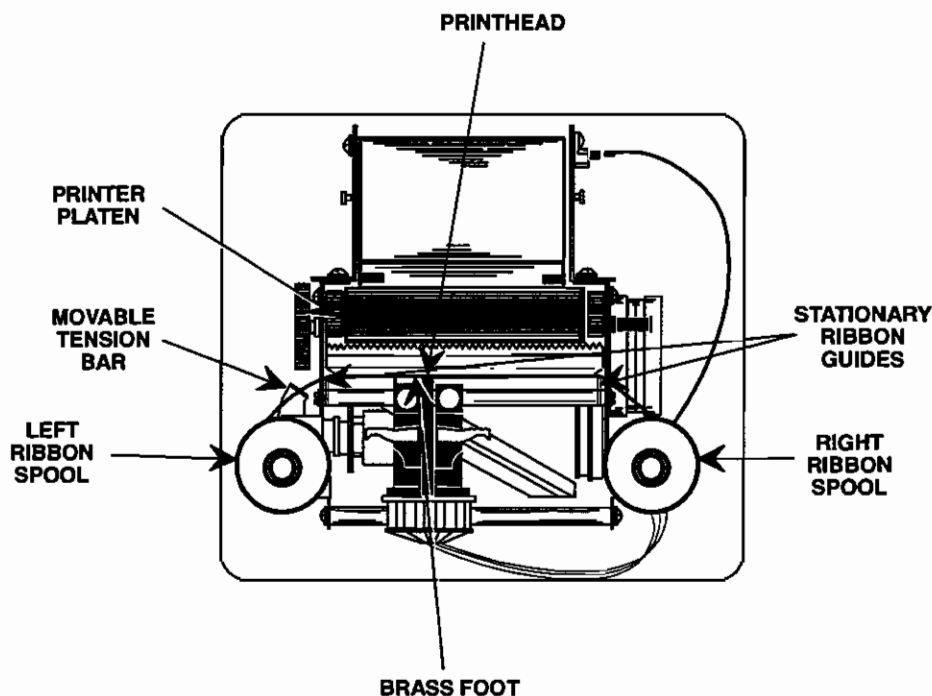
To perform this procedure:

1. Remove printer cover and remove empty paper roll from the bracket at the rear of the printer.
2. Insert the plastic spindle into a new paper roll.
3. Place the roll into the carriage with the paper feeding from the back and under the bottom of the roll.
4. Thread the paper under the cutter bar, and set the movable paper guides so they are just touching the edges of the paper. Be sure that the paper guide tabs (if present) are placed on top of the paper.
5. Advance the paper one line at a time by pressing **PRINT**.
6. Replace the printer cover.
7. Press **TEST 5.4.1 RUN** to check the operation of the printer. Press **STOP** to return to [READY].

NOTE: A 3 ⁷/₈ inch roll of replacement paper may be purchased at most stationery supply stores. (Use paper with a rough texture for best results, or order from Abbott using LN 9520-20.)

Printer Ribbon Replacement

1. Remove the printer cover. Note how the ribbon is threaded. Remove the used ribbon spools.
2. Insert the new spools, teeth down, onto the ribbon spindle.
3. Thread the ribbon following the figure below. The ribbon should pass:
 - a. to the right of the movable triangular tension bar
 - b. behind the ribbon guide at the left end of the printer
 - c. on top of the brass foot
 - d. between the print head and the paper
 - e. behind the ribbon guide at the right end of the printer
 - f. onto the right ribbon spool
4. Remove slack in the ribbon by turning the right ribbon spool (white) clockwise.
5. To check proper installation, press **TEST 5.4.1 RUN**. Press **STOP** to return to [READY].
6. Replace the printer cover.



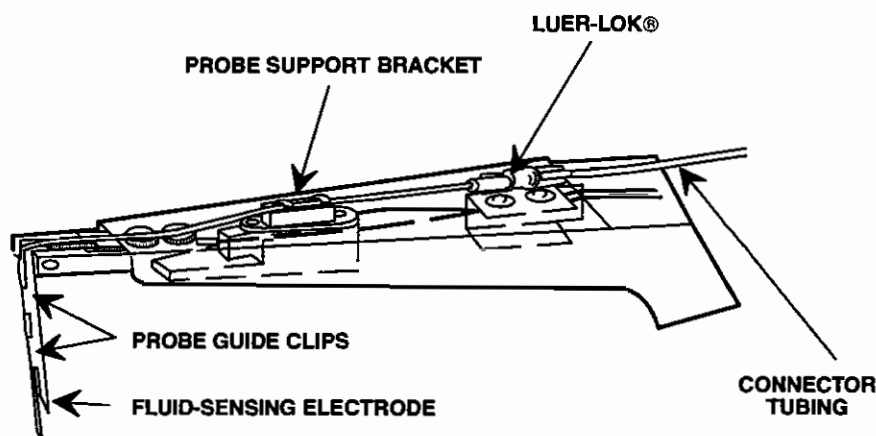
**Probe/Fluid-Sensing
Electrode****Probe Replacement**

Before beginning this procedure, remove the carousel from the TD_x analyzer, and move the boom arm to the center of the instrument by pulling on the boom arm or the barcode reader assembly.

1. Remove the stainless steel probe from the probe guide clips on the front of the fluid-sensing electrodes.
2. Remove the probe from the probe support bracket by pushing the probe to the right.
3. Unscrew the LUER-LOK[®] connecting the probe to the connector tubing by turning counterclockwise.
4. To attach the new probe, screw the LUER-LOK of the new probe into the connector tubing by turning clockwise.
5. Connect the probe to the fluid-sensing electrodes by snapping the probe guide into the probe-guide clips on the front of the electrodes.

| |
|---|
| DANGER: THE PROBE AND THE ELECTRODES ARE SHARP. TO PREVENT INJURY, USE CAUTION IN REMOVING AND REPLACING THEM. |
|---|

6. Secure the probe by inserting it into the two clips on the tubing support bracket.
7. Perform a Boom Calibration (Test 3.2) and a Unit Dose Boom Calibration (Test 3.6).
8. Perform the Probe Positioning Check and Adjustment procedure using the probe-positioning cartridge.
9. When a probe is replaced, recalibration of assays may be necessary. Check to be sure controls are in range.



Fluid-Sensing Electrode Replacement

1. Remove the probe from the probe guide clips and support bracket according to the directions given in the Probe Replacement instructions in this section.
2. Loosen the thumbscrew on the right side of the boom arm and remove the electrodes.

NOTE: If the thumbscrew was removed, be sure that the washer is replaced. Failure to place the washer between the thumbscrew and the boom arm can cause a liquid-level-sense (LLS) error.

3. Insert the new electrodes, pointed end down, into the boom arm.
Do not force the electrodes into position.

DANGER: THE PROBE AND THE ELECTRODES ARE SHARP. TO PREVENT INJURY, USE CAUTION IN REMOVING AND REPLACING THEM.

4. Tighten the thumbscrew on the right side of the boom arm until it is finger-tight.
5. Clip the probe into the detent of the fluid sensing electrodes. Replace the probe into the support bracket.
6. Perform a Z-boom Calibration (Test 3.5).

**Syringe Replacement
(diluent/sample) for
Analyzers Fitted with
Syringe Clamps**

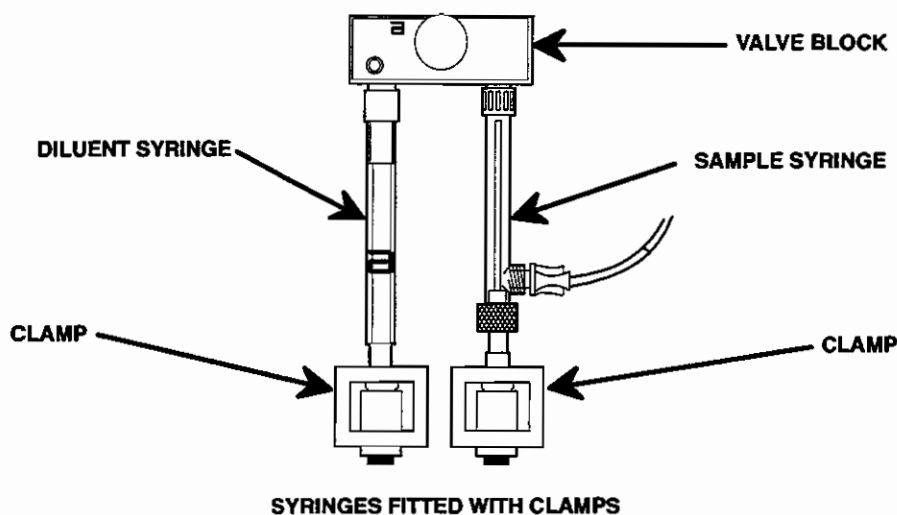
1. Remove the buffer access door and the buffer container.
2. For removal of the **sample** syringe **only**, proceed to step 6.
For removal of **both** syringes or **diluent** syringe **only**, continue to the next step.
3. Move the diluent syringe to the home (up) position:
 - a. Press **TEST 4.3 RUN** to activate dispenser assembly hand controls.
 - b. Place a test tube or other receptacle under the probe.
CAUTION: PLACING A TEST TUBE UNDER THE PROBE IS NECESSARY TO PREVENT BUFFER SPILLS INSIDE THE INSTRUMENT.
 - c. Press **0** to home the syringe and to dispense buffer into the test tube.
 - d. Remove and discard the test tube with buffer.
4. Move the diluent-syringe drive block down approximately 1 inch:
 - a. Press **7** to change from step to tab increments.
 - b. Press **4** (10 times) to move the syringe down.
5. If the sample syringe does **not** require removal, press **STOP** and proceed to step 7.
If the sample syringe must **also** be removed, move the sample-syringe drive block down approximately 1 inch:
 - a. Press **9** to activate control of the sample syringe.
 - b. Press **9** to change from step to tab increments.
 - c. Press **6** (10 times) to move the syringe down.
 - d. Press **STOP** to exit hand controls, and proceed to step 7.
6. Perform this step for removal of sample syringe only. Move the sample-syringe drive block down approximately 1 inch:
The drive block may be manually pushed down, or moved down using the following hand-control procedure:
 - a. Press **TEST 4.3 RUN** to activate dispenser assembly hand controls.
 - b. Press **9** to activate control of the sample syringe.
 - c. Press **6** (10 times) to move the syringe down.
 - d. Press **STOP** to exit hand controls.
7. Loosen the knurled screw on the appropriate syringe clamp(s), and remove the clamp(s).
8. Unscrew the syringe(s) from the valve housing, remove, and discard. If not removing the sample syringe, proceed to step 10. If removing the sample syringe, continue to the next step.

9. Remove the interconnect tubing:

- a. Unscrew the interconnect tubing from the plastic fitting on the sample syringe.
- b. If tubing is equipped with a plastic button, gently pull the plastic button off the left post of the liquid heater so that the interconnect tubing is exposed.
- c. Remove the interconnect tubing from the left post.
- d. Discard the tubing.
- e. Attach the new interconnect tubing to the left post of the liquid heater.

CAUTION: ENSURE TUBING IS ON SECURELY TO PREVENT LEAKS.

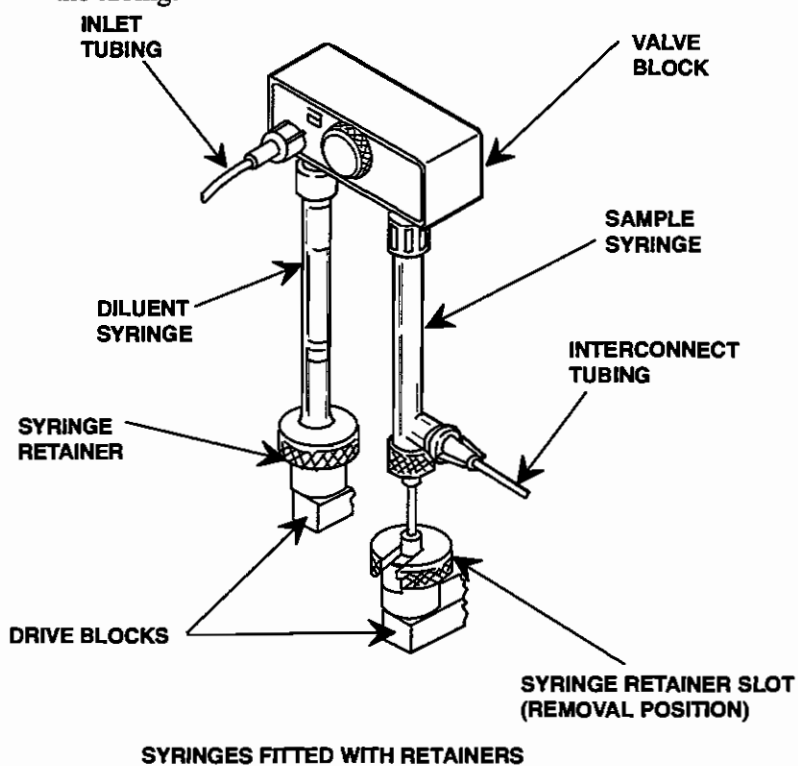
- f. Gently push the button, if so equipped, on the left post to secure the tubing.
10. Screw the new syringe(s) onto the valve housing. Ensure that each syringe is parallel to the back plate. If not, remove the syringe, and rotate it 180 degrees before reattaching.
 11. Pull the plunger(s) down, and seat it into the detent on top of the syringe drive block until it clicks into position.
 12. Place a clamp over the plunger(s), and tighten the knurled screw. Ensure that the clamps are straight and that each knurled screw is seated in the detent on the underside of the syringe block.
 13. Press **PRIME** (five times) to remove bubbles.
 14. Recalibration of assays may be necessary if either syringe is replaced. Check to be sure that controls are in range for each assay that is run.



**Syringe Replacement
(diluent/sample) for
Analyzers Fitted with
Syringe Retainers**

1. Remove the buffer access door and the buffer container.
2. For removal of the **sample** syringe **only**, proceed to step 6.
For removal of **both** syringes or **diluent** syringe **only**, continue to the next step.
3. Move the diluent syringe to the home (up) position:
 - a. Press **TEST 4.3 RUN** to activate dispenser assembly hand controls.
 - b. Place a test tube or other receptacle under the probe.
CAUTION: PLACING A TEST TUBE UNDER THE PROBE IS NECESSARY TO PREVENT BUFFER SPILLS INSIDE THE INSTRUMENT.
 - c. Press **0** to home the syringe and to dispense buffer into the test tube.
 - d. Remove and discard the test tube with buffer.
4. Move the diluent-syringe drive block down approximately 1 inch:
 - a. Press **7** to change from step to tab increments.
 - b. Press **4** (10 times) to move the syringe down.
5. If the sample syringe does **not** require removal, press **STOP** and proceed to step 7.
If the sample syringe must **also** be removed, move the sample-syringe drive block down approximately 1 inch:
 - a. Press **9** to activate control of the sample syringe.
 - b. Press **9** to change from step to tab increments.
 - c. Press **6** (10 times) to move the syringe down.
 - d. Press **STOP** to exit hand controls, and proceed to step 7.
6. Perform this step for removal of sample syringe only. Move the sample-syringe drive block down:
The drive block may be manually pushed down, or moved down using the following hand-control procedure:
 - a. Press **TEST 4.3 RUN** to activate dispenser assembly hand controls.
 - b. Press **9** to activate control of the sample syringe.
 - c. Press **6** (10 times) to move the syringe down.
 - d. Press **STOP** to exit hand controls.

7. Loosen the syringe retainer(s) by turning it clockwise one to two revolutions. Align the slot in the syringe retainer outward, facing toward the front of the analyzer.
 8. Unscrew the syringe(s) from the valve housing. To remove a syringe:
 - a. Push down on the syringe barrel until the top of the syringe is free of the valve block.
 - b. Slip the syringe plunger out of the syringe retainer slot, and discard the syringe.
 - c. If not removing the sample syringe, proceed to step 10. If removing the sample syringe, continue to the next step.
 9. Remove the interconnect tubing:
 - a. Unscrew the interconnect tubing from the plastic fitting on the sample syringe.
 - b. If tubing is equipped with a plastic button, gently pull the plastic button off the left post of the liquid heater so that the interconnect tubing is exposed.
 - c. Remove the interconnect tubing from the left post.
 - d. Discard the tubing.
 - e. Attach the new interconnect tubing to the left post of the liquid heater.
- CAUTION:** ENSURE TUBING IS ON SECURELY TO PREVENT LEAKS.
- f. Gently push the button, if so equipped, on the left post to secure the tubing.



10. Slip the plunger of the new syringe(s) into the syringe retainer(s).
11. Pull up or push down on the syringe until you are able to screw the new syringe onto the valve housing. Ensure that the syringe is parallel to the back plate.
12. Ensure that the syringe plunger is seated in the detent on the top of the syringe drive block, then tighten the syringe retainer by turning the syringe retainer counter-clockwise.
13. Replace the buffer container, and press **PRIME** (five times) to remove bubbles.
14. Recalibration of assays may be necessary if either syringe is replaced. Check to be sure that controls are in range for each assay that is run.

Tubing Replacement**Probe-Connector Tubing (LN 9968-01)**

1. Remove the probe from the probe guide clips and tubing support bracket according to the directions given in the Probe Replacement instructions in this section. Do not remove the fluid-sensing electrodes.
2. If tubing is equipped with a plastic button, gently pull the button off the right post of the liquid heater so that the probe connector tubing is exposed.
3. Remove the probe-connector tubing from the right post on the liquid heater. Unscrew the connector tubing from the probe assembly.
4. Attach the new connector tubing to the right post of the liquid heater.
5. Reinstall the probe following steps 4 through 6 under the Probe Replacement instructions in this section.
6. Prime to ensure the tubing does not leak.

Interconnect Tubing

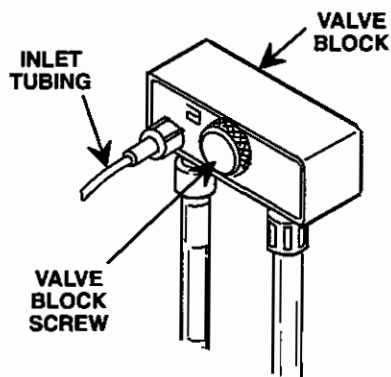
1. Unscrew the interconnect tubing from the sample syringe.
2. If tubing is equipped with a plastic button, gently pull the plastic button off the left post of the liquid heater so that the interconnect tubing is exposed.
3. Remove the interconnect tubing from the left post.
4. Discard the tubing.
5. Screw new interconnect tubing into the sample syringe.
6. Attach interconnect tubing to the left post of the liquid heater.
CAUTION: ENSURE TUBING IS ON SECURELY TO PREVENT LEAKS.
7. Gently push the button, if so equipped, on the left post to secure the tubing.
8. Prime several times to ensure the tubing does not leak and buffer is being dispensed from the probe.

Inlet Tubing

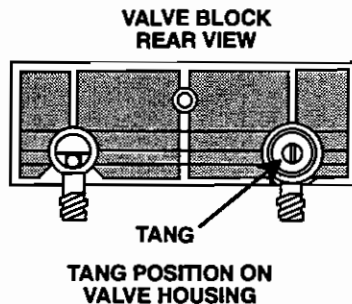
1. Unscrew the inlet tubing from the front left side of the valve block.
2. Allow remaining buffer to drain in the buffer bottle. Remove tubing from the buffer bottle and discard.
3. Attach new inlet tubing to the valve block.
4. Insert end of tubing into the buffer bottle.
5. Prime several times to ensure the tubing does not leak and buffer is being dispensed out the probe.

Valve Block Replacement

1. Unscrew the buffer inlet tubing from the valve housing. Remove the buffer container.

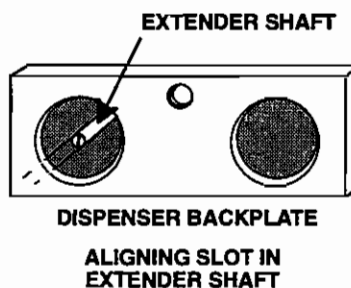


2. Remove both the sample and diluent syringes. Refer to the Syringe Replacement procedure in this section.
3. Unscrew and remove the valve block screw.
4. Pull the valve block off the dispenser and discard.
5. On the replacement valve, determine whether the metal tang on the inside of the right-hand valve is in a horizontal or vertical position.



6. Determine whether the slot in the valve extender shaft which protrudes out of the left-hand opening on the dispenser backplate is horizontal or vertical.
7. If both the tang and the slot are in the same position, install the valve block with syringe attachment connectors on the lower side. Tighten the valve block screw. Assure that the valve tang completely engages into the valve extender shaft and there is no space across the top of the valve between the valve and the dispenser backplate.

8. If the tang and the slot are not in the same position, using a blade screwdriver turn the extender shaft so that the slot is in the same position as the tang. Install the valve with the syringe attachment connectors on the lower side. Tighten the valve block thumbscrew.



9. Reattach both the sample and diluent syringes.
10. Screw the inlet tubing into the valve housing. Place the buffer container on platform and insert the inlet tubing all the way into the container.
11. Prime the instrument several times to assure buffer is being dispensed properly.

NOTES: If buffer does not prime after replacing the valve, recheck the valve tang and extender shaft positions. Also, ensure that the tube fittings are attached securely to avoid leaks.

If buffer still does not prime, remove the valve block and rotate the extender shaft 180 degrees, then reinstall the valve and syringes and prime the TD_x analyzer.

12. Recalibration of assays may be necessary when the valve block is replaced. Check to be sure controls are in range for each assay that is run.



Introduction

This section provides the information necessary to define, isolate, and resolve operational and component problems.

This information is presented in three categories:

1. **Displayed Error Codes** - Error codes that appear on the instrument's display.
2. **Printed Error Codes** - Error codes that are printed out during instrument operation.
3. **Observed Problems** - Problems that occur during operation.

Each section includes a description of the possible cause and likely resolution.

If after following all corrective action procedures, assistance is still required, contact the Customer Support Center.

Guidelines for using the troubleshooting guide:

- The final step for all troubleshooting corrective actions, whether stated or not, is to contact the Customer Support Center if a problem cannot be resolved. The telephone number is (800) 527-1869 (USA). For other areas of the world, please call your local Customer Service Department.
- For corrective actions that require performing a system or diagnostic check refer to Section IV, Diagnostic Checks.
- For corrective actions requiring cleaning, adjusting, checking, or replacing components, refer to Section V, Maintenance.
- If corrective actions require power interruption for 30 minutes or longer, the TD_x System should be allowed to warm up for 30 minutes after power is restored. Failure to do so may result in heater messages.



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| Code | A C HTR SPC FAIL |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Air heater continuously below specifications. |
| Corrective Action | <ol style="list-style-type: none"> 1. Air heater will automatically shut off. 2. Press STOP. Allow system to return to [READY] before continuing with normal operation. 3. If heater continues to be out of specification, call the Customer Support Center. |

| Code | A C HTR BRK FAIL |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Air heater continues to remain below specification for an extended period of time. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Call the Customer Support Center immediately. |

| Code | A H HTR SPC FAIL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Air heater continuously above specifications. |
| Corrective Action | <ol style="list-style-type: none"> 1. Air heater will automatically shut off. 2. Press STOP. Ensure at least 6" of space on all sides of the TD_x analyzer. Allow system to return to [READY] before continuing with normal operation. 3. Check to make sure nothing is blocking fan underneath the TD_x analyzer or nothing is blocking the right side of the TD_x analyzer. 4. Check to be sure the air-fan filter is clean. Wash filter if necessary. 5. Check to be sure the air-fan filter is properly seated. 6. If heater continues to be out of specification, call the Customer Support Center. |

For any procedure during which power to the TD_x System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.

| | |
|-------------------|---|
| Code | A H HTR BRK FAIL |
| Possible Cause | <ul style="list-style-type: none">• Air heater continues to remain above specification for an extended period of time. |
| Corrective Action | <ol style="list-style-type: none">1. Call the Customer Support Center immediately. |
| Code | A HTR FAILURE |
| Possible Cause | <ul style="list-style-type: none">• Air heater not operational. |
| Corrective Action | <ol style="list-style-type: none">1. Call the Customer Support Center immediately. |
| Code | AIR HTR T = |
| Possible Cause | <ul style="list-style-type: none">• Temperature of air heater when out of specification. |
| Corrective Action | <ol style="list-style-type: none">1. Momentarily displayed, repeat corrective action steps for air heaters SPC and BRK FAIL messages. |
| Code | ASSAYS DISAGREE |
| Possible Cause | <ul style="list-style-type: none">• If a unit dose cartridge is read as a different assay than the first cartridge read, during unit dose calibration. |
| Corrective Action | <ol style="list-style-type: none">1. When calibrating a unit dose assay, ensure all cartridges are for the same assay.2. Replace the cartridge causing the error or use the Barcode Override option. |
| Code | BARCODE FAIL |
| Possible Cause | <ul style="list-style-type: none">• No reagent pack in instrument.• Reagent pack, unit dose cartridge label, or carousel not seated properly.• Reagent pack label, unit dose cartridge, or carousel label not clean.• Barcode reader dirty.• Reagent pack vial insert not straight.• Label not seated properly.• Barcode reader not properly aligned. |

| | |
|-------------------|--|
| | <ul style="list-style-type: none"> Barcode reader not sensing. Barcode reader not seated in boom arm properly. Barcode reader reads a unit dose carousel as a batch carousel, then tries to find a reagent pack barcode label. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Reseat reagent pack. Check barcode reader or boom arm for obstruction and remove if found. Also check length of probe tubing. Clean label on reagent pack and carousel. (Use water dampened cotton swab.) Clean barcode reader. (Use water dampened cotton swab.) Straighten vial insert in reagent pack or use a new reagent pack. Use another carousel or reagent pack to see if problem still occurs. Disable door lock, pressing SYSTEM 2.2 EDIT 0 STORE STOP. Place reagent pack with vial caps removed and carousel into the instrument, leave access door open. Initiate a run and determine if error is occurring on carousel or reagent pack. Enable door lock, pressing SYSTEM 2.2 EDIT 1 STORE STOP. Use Test 4.4 to check amplitude and positioning (SYSTEM for reagent pack, PRIME for carousel). Perform Boom Cal (Test 3.2). Determine the white to black transition point and edit System 3.10, 3.11, 3.12, 3.13 as applicable. Use Barcode Override procedure if unable to correct problem. If unable to correct problem, call the Customer Support Center with details. |
| Code | BUFFER EMPTY |
| Possible Cause | <ul style="list-style-type: none"> Volume of buffer insufficient. Obstruction under buffer platform. Buffer platform bent. Buffer sensor failure. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Remove any obstruction found under platform. Replace buffer bottle. Press PRIME three times. |

5. If problem reoccurs with new buffer bottle, press **STOP**. Press **TEST 4.3 RUN 9**. Lift and reseal buffer twice to ensure buffer sensor resets.
6. If [B=Y] with buffer on the platform and [B=N] with no buffer on the platform, the buffer sensor is functioning, but the buffer platform needs adjusting.
7. Refer to Section V, Maintenance, under Adjustments/Checks for the Buffer Platform Adjustment procedure.
8. If unable to correct problem, call the Customer Support Center with details.

| | |
|-------------------|---|
| Code | BUFFER PRESENT |
| Possible Cause | <ul style="list-style-type: none"> • Did not lift buffer bottle when running Test 5.7. • Possible buffer sensor failure. |
| Corrective Action | <ol style="list-style-type: none"> 1. Repeat Test 5.7. 2. Lift the buffer bottle when prompted to do so by the display. 3. If unable to resolve problem, call the Customer Support Center. |
| Code | CALIB. ABORTED |
| Possible Cause | <ul style="list-style-type: none"> • During calibration, an error was encountered for each replicate of a calibrator level, therefore no concentration can be determined for that calibration. No further calibrators, controls or samples will be pipetted. |
| Corrective Action | <ol style="list-style-type: none"> 1. The error message(s) printed for the affected calibrator must first be addressed. See the appropriate section of this troubleshooting guide. 2. Repeat the calibration run, repipetting all calibrators and controls (using clean, previously unused cartridges and cuvettes). 3. If unable to resolve the problem, contact the Customer Support Center. |
| Code | CAL REPS BAD |
| Possible Cause | <ul style="list-style-type: none"> • This message will appear when System 4.2 is used to display calibration data and the criteria defined by assay parameter XX.6 is not met. |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed error message CAL REPS INCORRECT FOR CALIBRATION. |

| Code | CALVOL ILLEGAL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Calibration volume incorrect. |
| Corrective Action | <ol style="list-style-type: none"> 1. Edit calibration volume per the assay manual insert. 2. If unable to correct the problem, call the Customer Support Center. |
| Code | CAR LBL ERR-RUN? |
| Possible Cause | <ul style="list-style-type: none"> • Message displayed during Photo Calibration if a barcode read failure occurred or if the Fluorometric Standards Function Test Set Carousel is not in the TD_x analyzer. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP if a valid Fluorometric Standards Function Test Set Carousel is not in the TD_x analyzer. 2. Press RUN if a valid Fluorometric Standards Function Test Set Carousel is in place. |
| Code | CAR LBL READ ERR |
| Possible Cause | <ul style="list-style-type: none"> • Unlabeled carousel. • Carousel label not clean. • Carousel label on crooked. • Carousel label not flat. • Barcode reader dirty. • Barcode reader not sensing. • Barcode reader not seated in boom arm properly. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Assure that a properly labeled carousel is being used. 3. Clean carousel label. (Wipe with a water dampened cotton swab. Dry by pressing down firmly across the label with a clean cotton swab.) 4. Relabel carousel. 5. Use another carousel. 6. Clean barcode reader. 7. Perform Boom Calibration (Test 3.2). 8. Check barcode reader lateral adjustment. 9. Use Barcode Override procedure if unable to correct problem. 10. If problem occurs with all carousels, call the Customer Support Center. |

| Code | CAR POS ERROR |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> The location of the carousel does not match the correct position required to perform the run using Interactive Dilution Protocol. |
| Corrective Action | <ol style="list-style-type: none"> Repeat the run. If message reoccurs, call the Customer Support Center. |
| Code | CHECK WASTE CUP |
| Possible Cause | <ul style="list-style-type: none"> Normal message after approximately 25 prime cycles have been completed. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Empty waste cup and replace. Continue operation. |
| Code | CRSL NOT LOCKED |
| Possible Cause | <ul style="list-style-type: none"> Carousel not locked. Lock tab obstructed, dirty or coating worn. Sensor in optics assembly obstructed or dirty. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Remove carousel. Turn handle lock clockwise and return carousel to centerpost. Look for any obstruction and remove. Clean tab on carousel, if coating is worn, apply a coating of Liquid Paper®. Check photo sensor located at the 1 o'clock position in optics assembly for obstruction. Remove obstruction if possible. Clean sensor carefully with distilled water and cotton swab. If unable to correct problem, call the Customer Support Center. |

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| Code | CRSL STEP LOSS |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • There is an obstruction preventing carousel movement. • Carousel not properly seated on centerpost. • Carousel teeth have been damaged by dropping or melting. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Look for obstruction and remove. Reseat carousel on centerpost. 3. Clean carousel gear. 4. Check teeth underneath the carousel. If chipped, or otherwise damaged, replace the carousel. Clean the teeth if dried buffer is present. 5. Clean the carousel sensor located at the 9 o'clock position of the baseplate with a forced air source. Refer to Section V, Maintenance, for carousel home sensor cleaning. 6. If unable to correct problem, call the Customer Support Center. |
| Code | CUV MISCOUNT |
| Possible Cause | <ul style="list-style-type: none"> • The number of cuvettes on the carousel does not match the correct number of cuvettes required to perform the run using Interactive Dilution Protocol. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Ensure that the appropriate number of cuvettes are loaded on the carousel. 3. Continue operation. |
| Code | CUV SENSOR ERR |
| Possible Cause | <ul style="list-style-type: none"> • Tried to run Test 5.7 without Fluorometric Standards Function Test Set Carousel. • Optical sensor obstructed or malfunctioning. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Insert Fluorometric Standards Function Test Set Carousel and repeat Test 5.7. 3. Look for obstruction and remove. Clean optical sensor located at the 1 o'clock position in the optics assembly. 4. If unable to correct problem, call the Customer Support Center. |

| | |
|-------------------|--|
| Code | DATE ____ . ____ . ____ |
| Possible Cause | <ul style="list-style-type: none"> Instrument power has just been turned on. (Can occur after a momentary interruption of power.) |
| Corrective Action | <ol style="list-style-type: none"> Enter the date. Each entry must be two-digits separated by pressing the • key. When the date is entered correctly press STORE. Display shows [TIME ____ . ____ . ____]. Enter time using military (24 hour) time. Each entry must be two-digits separated by pressing the • key. When the time is entered, correctly press STORE. Display shows [READY], press PRIME. Begin operation as necessary. |

| | |
|-------------------|--|
| Code | DEG C < 30.0 |
| Possible Cause | <ul style="list-style-type: none"> Temperature entered during Temperature Calibration was less than 30.0°C. |
| Corrective Action | <ol style="list-style-type: none"> Press CLEAR. Reenter correct temperature. If unable to correct problem, call the Customer Support Center. |

| | |
|-------------------|--|
| Code | DEG C > 37.0 |
| Possible Cause | <ul style="list-style-type: none"> Temperature entered during Temperature Calibration was greater than 37.0°C. |
| Corrective Action | <ol style="list-style-type: none"> Press CLEAR. Reenter correct temperature. If unable to correct problem, call the Customer Support Center. |

| Code | DLNT JAMMED or DLNT NOT HME or DLNT STEP LOSS |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Long-term nonuse with salt buildup in dispenser components. • Valve malfunctioning. • Faulty diluent syringe seal. • Dispenser failure. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Press PRIME three times. 3. Inspect valve block and syringes for damage or salt build-up and replace as necessary. 4. If not corrected, replace diluent syringe. 5. If unable to correct problem, call the Customer Support Center. |

| Code | DONE-REMOVE RPAK |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Normal message that occurs at the end of a batch assay or calibration run. A beep will sound and the display returns to [READY]. |
| Corrective Action | <ol style="list-style-type: none"> 1. Open access door and remove reagent pack. Return pack to proper storage, per labeling. 2. Close access door. |

| Code | DOOR CLOSED |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Access door not opened properly in Test 5.7. • Optical sensor defective or misaligned. |
| Corrective Action | <ol style="list-style-type: none"> 1. Open access door and repeat Test 5.7. 2. Ensure the access door is fully opened when you are prompted by the display to open it. 3. If unable to correct the problem, call the Customer Support Center. |

| Code | DOOR OPEN |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Access door not completely closed. • Optical door sensor dirty. • Optical door sensor defective. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Close the access door. 3. Raise and lower access doors. 4. Clean the optical door sensor. 5. If troubleshooting with the access door open, close the access door for 10 seconds and then continue. 6. If the optical sensor has failed, disable the door lock using System 2.2 to run the assay. (Press SYSTEM 2.2 EDIT 0 STORE STOP.) 7. Call the Customer Support Center to report failure. |
| Code | ERR-STOP-FIX-GO |
| Possible Cause | <ul style="list-style-type: none"> • This message will be displayed if any barcodes on a unit dose cartridge are not read properly during an assay run. Occurs after all cartridges have been read. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press NEXT. The following will be displayed: <div data-bbox="781 1283 1167 1341" data-label="Text" style="border: 1px solid black; padding: 5px; text-align: center;"> LOC 1 ASSAY # ____ </div> <p>NOTE: The system will allow 15 seconds to begin to correct this error. If step 1 is not started within 15 seconds, the system will continue to the next position and the position causing the error will not be assayed.</p> <ol style="list-style-type: none"> 2. DO NOT OPEN DOOR. Check the printout to determine which cartridge is causing the error. BARCODE FAIL will be printed in place of the assay name for the cartridge in error. 3. Continue to press NEXT until the location of the cartridge causing the error message is displayed. 4. Enter the correct assay number for that cartridge and press STORE. 5. Repeat steps 3 and 4 for any other positions in error. 6. Press RUN to resume reading. A corrected list of assays will be printed. 7. If the list is correct when [ASSAY LIST OK?] appears in the display, press STORE to start the assay run. If the list is incorrect, repeat steps 3 and 4 above to enter the correct assay number. |

8. If barcode failures occur often, align the barcode reader by performing a Unit Dose Boom Calibration (Test 3.6). Refer to Section V, Maintenance, for the procedure.
9. If problem is not resolved, contact the Customer Support Center.

| Code | ERR-STOP OR FIX |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Occurs when any cartridge after position 1 cartridge is misread by the barcode reader during a Unit Dose Calibration run. |
| Corrective Action | <ol style="list-style-type: none"> Verify that all unit dose cartridges loaded on the carousel are of the same assay. If error recurs, press NEXT. The display reads: <div data-bbox="852 886 1240 945" data-label="Text" style="border: 1px solid black; padding: 5px; text-align: center;"> ASSAY # _ _ </div> Enter the correct assay number and press RUN. Calibration will begin. |

| Code | EXTRA CUVETTE(S) |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> When using the Unit Dose Barcode Override procedure, fewer positions are edited than are present on the carousel. When calibrating CRP, if controls or unknowns have been put on the carousel following the calibrators. |
| Corrective Action | <ol style="list-style-type: none"> Check carousel to ensure no used cuvettes remain from a previous run. Repeat the Unit Dose Barcode Override procedure ensuring that an assay number is entered for each position containing a unit dose cartridge. Repeat the CRP calibration ensuring that no controls or unknowns are put on the carousel. |

| Code | F TO D FAIL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Frequency to digital failure during temperature monitoring. |
| Corrective Action | <ol style="list-style-type: none"> Call the Customer Support Center with all information. |

| Code | F-SET IN PROCESS |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Factory set, Test 6.2 is being performed. |
| Corrective Action | <ol style="list-style-type: none"> 1. No corrective action. When software is upgraded, a factory set is required. System and assay parameters are set to their factory values. Assay calibration curves are not lost during this test. <p>NOTE: If the user wants to erase all assay calibration curves, this may be done by performing Test 6.5 (Zero Calibration Curve), along with Test 6.2.</p> <p>CAUTION: TESTS 6.2 AND 6.5 ARE INTENDED FOR FACTORY TESTING AND SERVICE ONLY. NEITHER OF THESE SHOULD BE PERFORMED WITHOUT FIRST CONSULTING THE CUSTOMER SUPPORT CENTER. OTHERWISE, DAMAGE TO THE INSTRUMENT COULD RESULT.</p> |
| Code | GAIN MISMATCH |
| Possible Cause | <ul style="list-style-type: none"> • Photo Check Gain (Test 2.2.1) did not match Photo Cal Gain (Test 3.4.1) when either test was run. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Edit Test 2.2.1 and Test 3.4.1, 3.4.2, and 3.4.4 parameters to match the values on the Fluorometric Standards Function Test Set Carousel label. |
| Code | ILLEGAL ASSAY |
| Possible Cause | <ul style="list-style-type: none"> • Attempting to run an assay with parameter .21 (MN TRACER) at 0. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Perform Pipet Check (Test 2.3) to set the MN TRACER parameter. 3. If unable to correct problem, call the Customer Support Center. |
| Code | ILLEGAL MODE |
| Possible Cause | <ul style="list-style-type: none"> • Attempting to run an assay with an undefined mode number for parameter .18 (MODE). • Attempting to reprint with System 4.1 when parameter .14 (CRV FIT) is 0 or 1. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Edit assay MODE with correct number, depending on the pipetting sequence required for the assay being run (see the Assay Parameters section in the assay manual insert for that assay). |

| Code | ILLEGAL UD LD LIST |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • FLM unit dose cartridges are loaded on the same carousel with another unit dose assay. • Ethosuximide unit dose cartridges are loaded on the same carousel with another unit dose assay. • Barcode label is misread as either FLM or Ethosuximide. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Remove the carousel from the TD_x analyzer. 3. Verify that either Ethosuximide or FLM unit dose cartridges are present on the carousel. If so, proceed to step 4. If Ethosuximide or FLM cartridges are not present, refer to Barcode Reader Lateral Adjustment Check in Section V, Maintenance. 4. Remove the FLM and/or Ethosuximide unit dose cartridge(s) from the carousel. 5. Reload the carousel. Reenter the carousel load list. FLM and Ethosuximide must be run as the only assay on the carousel and not in combination with each other or with any other unit dose assay. |
| Code | INSUFFIC SPL |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed message INSUFFICIENT SAMPLE. |
| Code | INVALID ASSAY |
| Possible Cause | <ul style="list-style-type: none"> • Attempting to run an assay or calibration before assay is activated. • Barcode reader misread reagent pack label as assay that has not been activated. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Use System 5 to activate assay if the MN TR (X.21) in the assay parameters is a value of zero. Call the Customer Support Center for activation code if necessary. 3. If the assay is activated, verify that the reagent pack name is being read correctly by the TD_x analyzer by using Test 4.4. SYSTM to read reagent pack label. If correct, press STOP and RUN. 4. If not being read correctly, follow corrective action under BARCODE FAIL. |

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| Code | INVALID CODE |
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| Possible Cause | <ul style="list-style-type: none">• Attempting to enter an incorrect code during edit function.• Attempting to enter an incorrect code during activation of assay number. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Proceed with editing assuring correct code is used. |

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| Code | INVAL CRVFIT # |
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| Possible Cause | <ul style="list-style-type: none">• Attempting to run a calibration curve with curve fit 0 or 1. |
| Corrective Action | <ol style="list-style-type: none">1. Do not attempt to edit curve fit to 0 or 1. Refer to the assay manual insert under the appropriate assay section for the correct curve fit. |

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| Code | INVALID DATE |
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| Possible Cause | <ul style="list-style-type: none">• Invalid date was entered on power up. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Press SYSTEM 1.1 EDIT. Enter valid date. |

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| Code | INVALID GAIN |
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| Possible Cause | <ul style="list-style-type: none">• Attempting to run Photo Cal or Photo Check with improper gain. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Edit Test 3.4.1 to gain indicated on Fluorometric Standards Function Test Set Carousel label.3. If running Photo Check, press STOP and edit Test 2.2.1 to match labeled value on Fluorometric Standards Function Test Set Carousel. |

| Code | KEEP DOOR CLOSED |
|---|---|
| Possible Cause | <ul style="list-style-type: none"> • This reminder occurs if the access door is open for 6 minutes or more. • If troubleshooting is to continue, close access door for 10 seconds before reopening. |
| Corrective Action | <ol style="list-style-type: none"> 1. Close the access door. 2. If access door is closed and error message remains, edit System 2.2 to 0 (off) and report failure to the Customer Support Center. |
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| <div data-bbox="607 711 1458 848" style="border: 1px solid black; padding: 5px;"> <p>For any procedure during which power to the TD_x System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.</p> </div> | |
| | |
| Code | L C HTR SPC FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Liquid heater continuously below specifications. |
| Corrective Action | <ol style="list-style-type: none"> 1. Liquid heater will automatically shut off. 2. Press STOP. Allow system to return to [READY] before continuing with normal operation. 3. Press PRIME three times. 4. If heater continues to be out of specification, call the Customer Support Center. |
| Code | L C HTR BRK FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Liquid heater continues to remain below specification for an extended period of time. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Call the Customer Support Center immediately. |

| Code | L H HTR SPC FAIL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Liquid heater continuously above specifications. |
| Corrective Action | <ol style="list-style-type: none"> 1. Liquid heater will automatically shut off. 2. Press STOP. Allow system to return to [READY] before continuing normal operation. 3. If heater continues to be out of specification, call the Customer Support Center. |
| Code | L H HTR BRK FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Liquid heater continues to remain above specifications for an extended period of time. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Call the Customer Support Center immediately. |
| Code | LIQ HTR T = |
| Possible Cause | <ul style="list-style-type: none"> • Temperature of liquid heater when out of specification. |
| Corrective Action | <ol style="list-style-type: none"> 1. Momentarily displayed, press PRIME several times. |
| Code | LAMP OUT |
| Possible Cause | <ul style="list-style-type: none"> • Burned out bulb. • Lamp not seated properly in housing. • Broken or very dirty bulb. • Contacts on bulb dirty or connection loose. • Aperture on left-hand wall of source lamp housing dirty. • If lamp is illuminated, may indicate damage to lamp or optics failure. |
| Corrective Action | <p>CAUTION: LAMP AND LAMP HOUSING CAN BE VERY HOT. ALLOW TO COOL BEFORE TOUCHING.</p> <ol style="list-style-type: none"> 1. Press STOP. 2. Check lamp operation by pressing TEST 4.2 RUN PRIME. If lamp turns on, check that lamp is properly seated. 3. Clean aperture lens on left hand wall inside source lamp housing with a damp cotton swab. 4. If hot, allow bulb to cool 10 minutes before touching. |

5. If problem still occurs, remove bulb, clean contacts with emery paper, and reseal lamp securely into connector.
6. Replace bulb. Refer to Section V, Maintenance.
7. If unable to correct problem, call the Customer Support Center with all information.

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| Code | LIQ SENSE ERROR |
| Corrective Action | 1. Refer to printed message LIQ SENSE ERROR. |

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|-------------------|---|
| Code | LIQ XTAL FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Failure of liquid crystal polarizer. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Rerun Photo Check (Test 2.2). 3. If unable to correct problem, call the Customer Support Center. |

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| Code | LIQUID LEVEL HI |
| Corrective Action | 1. Refer to printed error message LIQUID LEVEL HI. |

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| Code | LLS FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Liquid on probe is creating a liquid bridge between two electrodes. • Probe tip damaged or mispositioned. • Buffer salt bridge has formed between two electrodes. • Splashing in predilution chamber. • Used cuvettes not removed from carousel. • Inlet tube not seated all the way into buffer. • Undetected empty buffer bottle. • Probe thumbscrew not properly secured. • Thumbscrew washer missing. • Liquid-level-sensing electrodes not properly inserted into end of boom arm. • End of boom arm dirty from dried buffer salts. |

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| | <ul style="list-style-type: none"> • If displaying data using System 4.2, refer to LLS FAIL in printed messages. • During Dispense Check (Test 6.3) if liquid in all of the pots (reagent, sample, and predilute) is not sufficient. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Wash and dry probe. 3. Check cuvettes to be sure they were empty when the run started. 4. Push tube all the way into buffer. 5. Press PRIME three times, checking for air bubbles. Refer to procedure for air bubble removal. 6. Remove and reseal the probe; be sure thumbscrew on the right side of the boom arm is secure but not overtight. Ensure that there is an insulating washer between the thumbscrew and the boom arm. 7. Check probe position. Observe a buffer run. Adjust as needed. 8. Use Test 4.4 to check the fluid-sensing function of the probe and boom arm. 9. Remove probe and flush boom arm connection with distilled water. Thoroughly dry the boom and reattach the probe. 10. If not corrected, replace probe. 11. If unable to correct problem, call the Customer Support Center. |
| Code | > MX BKG |
| Possible Cause | <ul style="list-style-type: none"> • Occurs when System 4.2 is used to recall assay data for an abused drug assay and the BLK I is greater than assay parameter XX.20 (MX BKG). • Occurs when System 4.2 is used to recall data for an abused drug assay and assay parameter XX.3 (BKG FAC) is set to 0. |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed message > MX BKG. |

| Code | NET I LARGE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> This message will appear when System 4.2 is used to recall calibration data and the criteria defined by assay parameter .21 (MN TR) is not met. |
| Corrective Action | <ol style="list-style-type: none"> Refer to printed error message NET I LARGE. |
| Code | NET I SMALL |
| Possible Cause | <ul style="list-style-type: none"> This message will appear when System 4.2 is used to recall calibration data and the criteria defined by assay parameter .21 (MN TR) is not met. |
| Corrective Action | <ol style="list-style-type: none"> Refer to printed error message NET I TOO SMALL. |
| Code | NO CRSL |
| Possible Cause | <ul style="list-style-type: none"> No carousel in TD_x analyzer. Carousel not properly seated on centerpost. Carousel home optical sensor obstructed or dirty. Carousel home tab broken. Gear loose or obstruction on carousel stepper motor. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Insert or reseal carousel on centerpost. Look for and remove any obstruction near optical sensor which is located at 9 o'clock position on the base of the TD_x analyzer. Clean sensor if needed using forced air. Insert a different carousel. If unable to correct, call the Customer Support Center. |

| Code | NO CUV IN # |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Cuvette missing in carousel position (1–19) indicated. • Carousel dirty. • Optical sensor obstructed. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Place cuvette into appropriate position. 3. Look for and remove any obstruction near optical sensor located at the 1 o'clock position in optics assembly. 4. Wash carousel. 5. If running a Temperature Calibration (Test 3.1), a cuvette must be in positions 9, 10, and 11. 6. If unable to correct, call the Customer Support Center. |

| Code | NO DATA AVAIL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • After certain diagnostic and system tests, the assay or calibration data stored from the last run will not be allowed to reprint or be redisplayed. • During assay run, error occurred in all positions before any reading had taken place. No results available to reprint or display. |
| Corrective Action | <ol style="list-style-type: none"> 1. If reprint or redisplay of data is required do not initiate these tests until reprint or redisplay is completed. <ul style="list-style-type: none"> System 5 - Activate Assay System 6.2 - Assay Categories Test 1.2 - Life Test Test 2.1 - Temp Check Test 2.2 - Photo Check Test 3.1 - Temperature Calibration Test 3.2 - Boom Calibration Test 3.4 - Photo Calibration Test 3.8 - Turbo Carousel Calibration Test 5.2 - CPU Board Check Test 5.3 - Memory Board Check Test 5.4 - Printer and Driver Check Test 5.5 - Input/Output Board Check Test 5.6 - Front Panel Check Test 6 - Special Tests |

| Code | NO SPLS PIPETTED |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • No samples in sample cartridges. • Too little sample in sample cartridges to be detected. • R-boom not properly positioned. • Z-boom not properly positioned. • No sample detected in predilution well. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Remove carousel and check sample wells. 3. Add proper amount of sample to sample cartridge. 4. Ensure probe is properly installed in the boom arm and the thumbscrew is secure. 5. Check all connections in the dispenser assembly, especially tubing on liquid heater block. 6. Observe probe position in predilution well and sample well by performing a buffer run. 7. If problem persists, run Boom Calibration, Test 3.2, and ensure the probe is centered in the sample and predilution wells. 8. If problem persists check Z-boom position using Liquid-Level-Sensing Adjustment procedure or run Test 3.5 (Section IV) to recalibrate Z-boom home. 9. Check front to back probe positioning in predilution well. 10. If unable to correct problem, call the Customer Support Center. |

| Code | NO TRANSITION PT |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Barcode label not detected during Boom Calibration (Test 3.2). • Barcode label not detected during Unit Dose Boom Calibration (Test 3.6). • Barcode label not detected during 4-Pot Reagent Pack Boom Calibration (Test 3.7). • Using assay carousel instead of calibration carousel during Boom Calibration (Test 3.2). • Reagent pack label not seated properly. • Calibration carousel label not positioned properly. • Barcode labels dirty. • Barcode reader dirty. • Barcode reader not positioned properly. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Ensure a calibration carousel is being used in the Boom Calibration procedure. 3. Check reagent pack for proper seating. 4. Check label on carousel for proper positioning. 5. Check both reagent pack and carousel labels to be sure they are clean and flat. Press down firmly across the label. 6. Clean barcode reader with a water dampened cotton swab. 7. Repeat Boom Calibration while watching operation. Note which label (reagent pack or carousel) failed. If unable to correct problem, refer to "Boom Calibration won't work properly" in Observed Problems section. 8. If carousel fails, use a new CAL carousel to run Boom Calibration. Check the memory for Test 3.2 and edit the value in Test 3.2.5 to 217, and the value in Test 3.2.6 to 1697 if necessary. 9. If reagent pack fails, edit Test 3.2.1 RPK ST step # to a value less than 20 steps to the left of the start of the reagent pack label. (Use Test 4.1 or 4.4 to determine the start of the reagent pack label.) 10. If [CONTINUE?] appears in the display after several seconds when running Test 3.6 and 3.7, press STORE to continue, otherwise, press STOP. 11. If unable to correct problem, call the Customer Support Center. |

| Code | NOT A PROGRAM |
|--|--|
| Possible Cause | <ul style="list-style-type: none"> • RUN pressed during displaying or editing of system, assay, or test parameters. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Complete editing of parameters. 3. When display shows [READY] proceed with run. 4. If unable to correct problem, call the Customer Support Center. |
| Code | NOVRAM ERROR |
| Possible Cause | <ul style="list-style-type: none"> • NOVRAM will not accept calibration data. |
| Corrective Action | <ol style="list-style-type: none"> 1. See NOVRAM ERRORS under Observed Problems for possible causes. |
| Code | O C HTR SPC FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Optical heater continuously below specifications. |
| Corrective Action | <ol style="list-style-type: none"> 1. Optical heater will automatically shut off. 2. Press STOP. Allow system to return to [READY] before continuing with normal operation. 3. If heater continues to be out of specification, call the Customer Support Center. |
| Code | O C HTR BRK FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Optical heater continues to remain below specification for an extended period of time. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP 2. Call Customer Support Center immediately. |
| <div style="border: 1px solid black; padding: 5px;"> <p>For any procedure during which power to the TD_x System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.</p> </div> | |

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|-------------------|---|
| Code | O H HTR SPC FAIL |
| Possible Cause | <ul style="list-style-type: none">• Optical heater continuously above specifications. |
| Corrective Action | <ol style="list-style-type: none">1. Optical heater will automatically shut off.2. Press STOP. Allow system to return to [READY] before continuing normal operation.3. If heater continues to be out of specification, call the Customer Support Center. |

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|-------------------|---|
| Code | O H HTR BRK FAIL |
| Possible Cause | <ul style="list-style-type: none">• Optical heater continues to remain above specifications for an extended period of time. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Call the Customer Support Center immediately. |

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|-------------------|---|
| Code | OPT HTR T = |
| Possible Cause | <ul style="list-style-type: none">• Temperature of optical heater when out of specification. |
| Corrective Action | <ol style="list-style-type: none">1. Momentarily displayed, repeat corrective action steps for the optical heaters SPC and BRK FAIL messages. |

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| Code | OVERFLOW |
| Possible Cause | <ul style="list-style-type: none">• Attempting to store too large a number during EDIT. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Edit parameter correctly.3. If unable to correct problem, call the Customer Support Center. |

| Code | PAK LBL READ ERR |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none">• No reagent pack in instrument.• Reagent pack not seated properly.• Label not clean on reagent pack.• Bubble under label on reagent pack.• Reagent pack vial insert crooked.• Barcode reader dirty.• Barcode reader not positioned properly over reagent pack label.• System 3.10 and 3.11 are not the same value.• Barcode reader in boom arm not at proper height.• Barcode reader not sensing. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Ensure reagent pack is present and properly seated.3. Remove reagent pack. Wipe label to remove any dirt. Press finger along label to remove any air bubbles. Proceed with run.4. Straighten vial insert in reagent pack or use a new reagent pack.5. Clean barcode reader with a damp cotton swab.6. Use another reagent pack to see if problem still occurs.7. If the barcode reader turns on (red dots show on pack label), run Boom Cal (Test 3.2).8. Refer to Barcode Reader Lateral Adjustment Check procedure.9. Use Barcode Override procedure if unable to correct problem.10. If problem occurs with all reagent packs, call the Customer Support Center. |

| Code | PAPER OUT |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• Insufficient paper in printer.• Paper not installed correctly.• Wires pulled off paper sensor connector.• Paper sensor failure. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Install new roll of printer paper.3. Press RUN.4. Reseat wires onto paper sensor connectors.5. Remove paper roll and tape paper sensor contact. If problem is corrected, gently bend metal plate (with paper sensor) toward center of printer. Remove tape. Reinstall paper roll.6. If unable to correct problem, call the Customer Support Center. |

| Code | PO TOO SMALL |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none">• This message will appear when System 4.2 is used to display calibration data and the criteria defined by assay parameter .16 (MN POLA) is not met. |
| Corrective Action | <ol style="list-style-type: none">1. Refer to printed error message PO TOO SMALL. |

| Code | PREDIL LEVEL HI |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none">1. Refer to printed error message PREDIL LEVEL HI. |

| Code | PREDIL LEVEL LO |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none">1. Refer to printed error message PREDIL LEVEL LO. |

| Code | PUNC INCOMPLETE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Occurs when the software determines the probe cannot drop the System 8.8 specified number of steps after first detecting foil without first getting to the liquid level low limit specified by System 8.10. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Check that the cartridge is intact and in no way damaged. 3. Check the position of the probe and correct as necessary. 4. Perform a Z-boom Calibration. 5. Replace fluid-sensing electrodes if necessary. 6. Call the Customer Support Center. |
| Code | RBM JMD HME or RBM NOT HME or RBM STEP LOSS |
| Possible Cause | <ul style="list-style-type: none"> Possible obstruction preventing boom arm from moving horizontally. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Look for obstruction and remove. 3. Check for sufficient length of probe tubing. If too short, replace probe or tubing as applicable. 4. If unable to correct problem, call the Customer Support Center. |
| Code | REAGENT LEVEL LO |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed message REAGENT LEVEL LO. |
| Code | REMOVE CAROUSEL |
| Possible Cause | <ul style="list-style-type: none"> Carousel has been left in TD_x analyzer for more than 5 minutes after a completed test run. |
| Corrective Action | <ol style="list-style-type: none"> 1. Remove the carousel. 2. If problem persists after removing the carousel, call the Customer Support Center. |

| Code | RGNT TOO FULL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Vial not seated fully down into pack. • Liquid film or air bubbles in vial opening. • Reagent pack not seated properly. • Probe wet. • Probe not properly seated in end of boom arm. • Probe thumbscrew loose. • Boom arm connectors dirty. • Z-boom not properly positioned. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Remove reagent pack from instrument. 3. Break liquid film over vial opening. 4. Push vial down into reagent pack. Replace reagent pack into instrument. 5. Clean and dry probe. 6. Press PRIME three times. 7. Check that the probe is secured to the boom arm. 8. Remove probe and flush end of boom arm with water. Thoroughly dry with a tissue. 9. Perform Z-boom Calibration procedure (Test 3.5). 10. If problem occurs with all reagent packs and no liquid has been added, replace the probe. 11. If unable to correct problem, call the Customer Support Center. |

| Code | RNG TOO LARGE |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • This message will appear when System 4.2 is used to redisplay calibration data and the criteria defined by assay parameter .15 (MX DEV) is not met. |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed error message RANGE TOO LARGE. |

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| Code | SPAN TOO SMALL |
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| Possible Cause | <ul style="list-style-type: none"> This message will appear when System 4.2 is used to recall calibration data and the criteria defined by assay parameter .17 (MN SPAN) is not met. |
| Corrective Action | <ol style="list-style-type: none"> Refer to printed error message SPAN LESS THAN MIN SPAN. |

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| Code | SPL CRTRDGE MISS |
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| Possible Cause | <ul style="list-style-type: none"> Sample cartridge missing during a run using Interactive Dilution Protocol. |
| Corrective Action | <ol style="list-style-type: none"> Inspect the carousel, and discard the affected cartridges and cuvettes. Load the cartridges and cuvettes, ensuring that all sample cartridges are present. If unable to resolve the problem, call the Customer Support Center. |

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| Code | SPL SYR JAMMED or SPL SYR NOT HME or SPL SYR STP LOSS |
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|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Long-term nonuse with salt buildup. Faulty sample syringe seal. Valve malfunctioning. Dispenser failure. Liquid heater or probe plugged. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Replace sample syringe. Press PRIME three times. Ensure buffer is coming out of the tip of the probe. Replace valve block. If unable to correct problem, call the Customer Support Center. |

| Code | SPLVOL ILLEGAL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Attempting to perform Dilution Protocol for assay that does not have protocol available. Incorrect sample volume programmed into assay parameters for pipetting mode being used. <ul style="list-style-type: none"> Mode 1 must be .2 μL to 20 μL Mode 2 must be 2 μL to 180 μL Mode 3 must be 5 μL to 145 μL Mode 4 must be .2 μL to 20 μL Mode 5 must be .2 μL to 350 μL Mode 6 must be 20 to 350 μL Mode 7 must be 3 μL to 105 μL Mode 8 must be 2 μL to 175 μL Mode 9 must be 100 μL to 350 μL Mode 10 must be 5 μL to 175 μL Mode 11 must be 2 μL to 180 μL Mode 12 must be .2 μL to 350 μL Mode 17 must be .2 μL to 20 μL Mode 19 must be 2 μL to 180 μL Mode 21 must be .2 μL to 350 μL Mode 22 must be .2 to 350 μL Mode 23 must be 50 to 450 μL Mode 25 must be 2 μL to 20 μL Mode 26 must be .5 μL to 20 μL Mode 27 must be .5 μL to 20 μL Mode 28 must be 2 μL to 20 μL Mode 30 must be 2 μL to 180 μL Mode 31 must be .8 μL to 1.7 μL Mode 33 must be .2 μL to 20 μL* Mode 37 must be 2 μL to 180 μL Mode 40 must be 16 μL Mode 42 must be 2 to 20 μL Mode 43 must be 2 to 20 μL <p>*For Benzodiazepines serum, Mode 33 sample volume must be .6 μL to 20 μL.</p> |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Refer to the assay manual insert for the correct sample volume required for the assay and for Dilution Protocol availability. Edit sample volume parameter ASSAY XX.1 to correct volume. Proceed with test run. |

| Code | SPLS NOT MONOT |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• This message will appear when System 4.2 is used to redisplay calibration data and the polarization did not change in a constant direction. |
| Corrective Action | <ol style="list-style-type: none">1. Refer to printed error message SPLS NOT MONOTONIC. |

| Code | TEMP CAL FAIL |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> When running Temp Cal (Test 3.1): <ul style="list-style-type: none"> Incorrect temperature entered. A large THM OFF value change was necessary. Carousel moved during calibration. Ambient temperature affecting the degrees C entered. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Repeat Temp Cal a couple of times with fresh cuvettes. If unable to resolve the problem, call the Customer Support Center. |

| Code | TEMP STABILIZING |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> If a heater is momentarily out of specification. |
| Corrective Action | <ol style="list-style-type: none"> An informative message, no action necessary. Ensure all environmental specifications for the TD_x analyzer are being met. |

| Code | TIME ____ . ____ . ____ |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Instrument power has just been turned on. Can occur after a momentary interruption of power. |
| Corrective Action | <ol style="list-style-type: none"> Enter time of day, using military (24-hour) time and press STORE. Display shows [READY], press PRIME. Begin operation as necessary. |

| Code | TOO FEW CUVETTES |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Incorrect number of cuvettes for a calibration run. Incorrect number of cuvettes for a Test 3 calibration procedure. Optical sensor dirty or obstructed. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Put correct number of cuvettes into carousel and lock it. Ensure CAL REP assay parameter (.6) is set correctly for mode of operation (batch or unit dose). Look for and remove any obstruction near cuvette optical sensor. If unable to correct problem, call the Customer Support Center. |

| Code | TOO LITTLE RGNT |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Too little reagent left in reagent pack to run the number of cuvettes present on the carousel. • Vial cap liner left on top of vial. • R-boom or Z-boom not properly positioned. • Probe failed to sense fluid properly. • Probe not attached in boom arm properly. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Remove samples one at a time until the run is initiated. (Too many cuvettes are present for the remaining reagent level.) 3. Remove empty reagent pack. Place new reagent pack into TD_x analyzer. 4. Remove cap liner from vial. 5. Perform Boom Calibration (Test 3.2). 6. Check probe position from front to back with probe-positioning cartridge. 7. If problem occurs with new reagent pack, wash and dry probe. Check the probe attachment. If problem still not corrected, replace probe. 8. If unable to correct problem, call the Customer Support Center. |

| Code | > = THRSILD |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Occurs when System 4.2 is used to recall assay data for an abused drug assay and System 6.7 (T PRINT) is set at 1. |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed message > = THRESHOLD. |

| Code | > T |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Occurs when System 4.2 is used to recall assay data for an abused drug assay and System 6.7 (T PRINT) is set at 0. |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed message > = T. |

| Code | VALVE JAMMED or VALVE NOT HOME or VALVE STEP LOSS |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• Valve core frozen with dried buffer.• Valve failure. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Press PRIME three times.3. If problem still occurs, replace valve assembly.4. If unable to correct problem, call the Customer Support Center. |
| Code | WRONG NUMBER |
| Possible Cause | <ul style="list-style-type: none">• Nothing in memory corresponds to the number entered. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Continue editing parameters after confirming correct code number.3. Enter only carousel number 1 to 10 during barcode override. |

| Code | WRONG PAK TYP |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • No reagent pack in instrument. • Reagent pack not seated properly. • Label not clean on reagent pack. • Bubble under label on reagent pack. • Reagent pack vial inserted crooked. • Barcode reader dirty. • Barcode reader unable to read label. • System 3.10 and 3.11 are not the same. • Barcode reader starting in wrong position. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Remove reagent pack. Wipe label to remove any dirt. Slide finger along label to remove any air bubbles. 3. Straighten vial insert in reagent pack or use new reagent pack. 4. Clean barcode reader with dampened cotton swab. 5. Check System 3 parameters .10 and .11. If they are not the same, set parameter .10 to equal parameter .11. Refer to Section V, Maintenance, under Barcode Reader Lateral Adjustment Check, to determine correct parameters. 6. Edit System 2.2 to "0". Leave access door open and initiate run. Observe barcode reader as it reads the reagent pack label. If it turns on, red dots will show on the reagent pack label. Perform a Boom Calibration (Test 3.2). Edit System 2.2 to "1". 7. Use Barcode Override procedure. 8. If problem occurs with all reagent packs, call the Customer Support Center. |

| Code | WRT OVER BOUNDARY |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Attempting to edit software that cannot be edited. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Call the Customer Support Center. |

| Code | WRT PROTECT |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Attempting to edit a parameter which cannot be edited. Attempting to edit a curve fit parameter which is outside of the range (0 to 15). Attempting to edit System 6.1 Serial #. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Continue normal operation. |

| Code | Z BM JAMMED or Z BM NOT HME or Z BM STEP LOSS |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Possible obstruction preventing boom arm from moving vertically. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Look for obstruction and remove. If unable to correct problem, call the Customer Support Center. |

| Code | > or < |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Attempting to edit a value which is outside the acceptable range for that parameter. If symbol is in right side of display refer to the Observed Problems in this section. |
| Corrective Action | <ol style="list-style-type: none"> Press STOP. Continue normal operation after verifying value being edited. |

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| Code | AVG I TOO LARGE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • During Photo Calibration (Test 3.4), Average Intensity measured was too large. • Test 3.4 parameters do not match value on carousel label. • Gain in Test 2.2.1 and Test 3.4.1 does not match label on Fluorometric Standards Function Test Set Carousel. • Stray light causing interference with optical readings. • Damaged or malfunctioning Fluorometric Standards Function Test Set Carousel. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Print Test 3.4 and check that the gain (3.4.1), intensity (3.4.2) and polarization (3.4.4) values match the values on the Fluorometric Standards Function Test Set Carousel label. 3. Print Test 2.2 and check that the gain (2.2.1) value matches the Fluorometric Standards Function Test Set Carousel label. 4. Edit any parameters which do not match so the instrument parameters are the same as the Fluorometric Standards Function Test Set Carousel label. 5. Rerun Test 3.4. 6. Check to be sure access door is properly seated. Also check that lamp cover is properly seated. 7. Check ampules in carousel for cracks or leaks. If found, order a new Fluorometric Standards Function Test Set Carousel (LN 9520-31). 8. If carousel has not been stored in box, place in box and rerun Photo Calibration in 1 hour. 9. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the Customer Support Center. 10. If unable to correct problem, call the Customer Support Center. |

| Code | AVG I TOO LARGE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • During Pipet Check (Test 2.3), the Average Intensity of locations 16-20 was greater than 10,000. • Dispenser not functioning properly. • Photo Calibration performed with wrong parameters (Test 3.4.1, 3.4.2 and 3.4.4) in memory. |
| Corrective Action | <ol style="list-style-type: none"> 1. Use another vial of Pipet Check Solution (LN 9531-02). 2. Check tubing and dispenser for leaks or slippage. 3. Check to be sure access door is properly seated. Also check that lamp cover is properly seated. 4. Run Photo Check (Test 2.2). 5. Run Photo Cal (Test 3.4). Repeat Photo Check (Test 2.2). 6. Repeat Pipet Check. 7. Replace dispenser components one at a time in the following order: <ol style="list-style-type: none"> a. Probe b. Sample Syringe c. Diluent Syringe d. Valve Block 8. Repeat Pipet Check. 9. If unable to correct the problem, call the Customer Support Center. |
| Code | AVG I TOO SMALL |
| Possible Cause | <ul style="list-style-type: none"> • During Photo Calibration (Test 3.4), Average Intensity measured was too small. • Test 3.4 parameters do not match value on label. • Gain in Test 2.2.1 and 3.4.1 does not match label on Fluorometric Standards Function Test Set Carousel. • Insufficient light reaching detector. • Damaged or malfunctioning Fluorometric Standards Function Test Set Carousel. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Print Test 3.4 and check that the gain (3.4.1), intensity (3.4.2) and polarization (3.4.4) values match the values on the Fluorometric Standards Function Test Set Carousel label. 3. Print Test 2.2 and check that gain (2.2.1) value matches the Fluorometric Standards Function Test Set Carousel label. |

4. Edit any parameters which do not match so the instrument parameters are the same as the Fluorometric Standards Function Test Set Carousel label.
5. Rerun Test 3.4.
6. Check lamp to assure it is properly installed. Look for and remove any obstruction found on the lens on the left wall inside the lamp housing.
7. Replace the source lamp.
8. Check ampules in carousel for cracks or leaks. If found, order a new Fluorometric Standards Function Test Set Carousel (LN 9520-31).
9. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the Customer Support Center.
10. If unable to correct problem call the Customer Support Center.

| Code | AVG I TOO SMALL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • During Pipet Check (Test 2.3), the Average Intensity of locations 16-20 was less than 4,000. • Dispenser not functioning properly. • Photo Cal performed with wrong parameters (Test 3.4.1, 3.4.2 and 3.4.4) in memory. |
| Corrective Action | <ol style="list-style-type: none"> 1. Use another vial of Pipet Check Solution (LN 9531-02). 2. Check lamp to ensure it is properly seated. Look for and remove any obstruction found on the lenses, including the lens on the inside left wall of the source lamp housing. 3. Replace source lamp. 4. Run Photo Check (Test 2.2). 5. Run Photo Cal (Test 3.4). Repeat Photo Check (Test 2.2). 6. Repeat Pipet Check. 7. Replace dispenser components one at a time in the following order: <ol style="list-style-type: none"> a. Probe b. Sample Syringe c. Diluent Syringe d. Valve Block 8. Repeat Pipet Check. 9. If unable to correct problem, call the Customer Support Center. |

| Code | AVG P TOO LARGE |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • During Photo Calibration (Test 3.4), Average Polarization measured was too large. • Test 3.4 parameters do not match value on label. • Liquid crystal is not operating properly. • Damaged or malfunctioning Fluorometric Standards Function Test Set Carousel. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Print Test 3.4 and check that the gain (3.4.1), intensity (3.4.2) and polarization (3.4.4) values match the values on the Fluorometric Standards Function Test Set Carousel label. 3. Edit any parameters which do not match so the instrument parameters are the same as the Fluorometric Standards Function Test Set Carousel label. 4. Rerun Test 3.4. 5. Check ampules in carousel for cracks or leaks. If found, order a new Fluorometric Standards Function Test Set Carousel (LN 9520-31). 6. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the Customer Support Center. 7. If unable to correct problem, call the Customer Support Center. |
| Code | AVG P TOO SMALL |
| Possible Cause | <ul style="list-style-type: none"> • During Photo Calibration (Test 3.4), Average Polarization measured too small. • Test 3.4 parameters do not match value on label. • Liquid crystal not operating properly. • Damaged or malfunctioning Fluorometric Standards Function Test Set Carousel. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Print Test 3.4 and check that the gain (3.4.1), intensity (3.4.2) and polarization (3.4.4) values match the values on the Fluorometric Standards Function Test Set Carousel label (LN 9520-31). 3. Edit any parameters which do not match so the instrument parameters are the same as the Fluorometric Standards Function Test Set Carousel label. 4. Rerun Test 3.4. |

5. Check ampules in carousel for cracks or leaks. If found, order a new Fluorometric Standards Function Test Set Carousel (LN 9520-31).
6. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the Customer Support Center.
7. If unable to correct problem, call the Customer Support Center.

| Code | BACKGROUND TOO LARGE |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • During calibration, background intensity exceeded assay parameter XX.20 (MX BKG). • During calibration of an abused drug assay, parameter XX.3 (BKG FAC) is set to 0. • Door not closed. • Parameter not correct. • Failure to discard used cuvettes. • Lamp cover not properly seated. • Inlet tube not seated all the way into buffer. • Reagents not in correct order, S, T, P. • Contaminated buffer carton. |
| Corrective Action | <ol style="list-style-type: none"> 1. Check assay parameter XX.3 (BKG FAC) for the abused drug assay being run. If parameter XX.3 (BKG FAC) is set to 0, call the Customer Support Center for the proper value. 2. Open access door. 3. Reseat lamp cover. 4. Close door securely. 5. Ensure that System 2.2 parameter is set to 1. 6. Check assay parameter XX.20 in the assay manual insert for assay being run. If it is not correctly programmed in the TD_x analyzer, edit the value to agree with the assay manual insert. 7. Push inlet tube all the way into buffer, press PRIME two or three times. 8. Use new reagent pack and calibrators. 9. If problem occurs with more than one assay, use new container of buffer. 10. Run Pipet Check (Test 2.3). 11. If unable to correct problem, call the Customer Support Center. |

| Barcode Fail | |
|-------------------------------------|---|
| Code | BARCODE FAIL |
| Possible Cause | <ul style="list-style-type: none"> • Missing a unit dose cartridge. • Unit dose cartridge barcode label is misread by the barcode reader. |
| Corrective Action | <ol style="list-style-type: none"> 1. Use the Barcode Override procedure. 2. Perform the Unit Dose Boom Calibration procedure (Test 3.6). 3. Replace the cartridge causing the error. |
| Below 1 | |
| Code | BELOW 1 |
| Possible Cause | <ul style="list-style-type: none"> • When running the Total T₃ PLUS assay with System 6.8 (TOT T₃) set at 1, and the concentration is less than 1.0 ng/mL. |
| Corrective Action | <ol style="list-style-type: none"> 1. A message signifying that the result is less than 1.0 ng/mL. No action necessary. |
| BLK I HI ALERT | |
| Code | BLK I HI ALERT |
| Possible Cause | <ul style="list-style-type: none"> • When running the CRP assay, a sample gives a BLK I reading greater than 1600.00 (MX BKG, parameter 53.20). |
| Corrective Action | <ol style="list-style-type: none"> 1. These samples should not be diluted. 2. Call the Customer Support Center. |
| Cal Repts Incorrect for Calibration | |
| Code | CAL REPS INCORRECT FOR CALIBRATION |
| Possible Cause | <ul style="list-style-type: none"> • During calibration, correct number of samples were not detected. Correct number of samples = 6 times CAL REP, (assay parameter XX.6). • Sample skipped on one or more calibrators. • Wrong number of replicates put into sample cartridges. • Probe not properly inserted into end of boom arm. • Probe position not correct in sample or predilution well. |
| Corrective Action | <ol style="list-style-type: none"> 1. Set up carousel with sufficient cuvettes to run all samples. Ensure that at least the minimum sample volume is used in the sample well. 2. Prepare carousel with new calibrators, ensuring that pipettors are dispensing the minimum volume required accurately. |

3. Wash and dry probe. Check probe to ensure it is properly attached in boom arm.
4. Press **PRIME** and observe dispenser for possible leaks or slipping syringe. Correct problem as applicable.
5. Run Dispense Check (Test 6.3) or observe "Buffer Run" for proper probe positioning and adjust as needed.
6. Run Boom Calibration, Test 3.2.
7. Replace probe.
8. If unable to correct problem, call the Customer Support Center.

Code

CALIBRATION ABORTED

Possible Cause

- During calibration, an error was encountered for each replicate of a calibrator level; therefore, no concentration can be determined for that calibrator. No further calibrators, controls or samples will be pipetted.

Corrective Action

1. The error message(s) printed for the affected calibrator must first be addressed. See the appropriate section of this troubleshooting guide.
2. Repeat the calibration run, repipetting all calibrators and controls (using clean, previously unused cartridges and cuvettes).
3. If unable to resolve problem, contact the Customer Support Center.

Code

CHECK DATA

Possible Cause

- Either the T4 or T-Uptake concentration was zero when calculating the FTI.
- Either the T4 or T-Uptake position did not give a reasonable concentration.
- T-Uptake was not the next assay run after T4.
- The TD_x analyzer lost power between T4 and T-Uptake runs.

Corrective Action

1. Check the T-Uptake units printed for the position.
2. Check the T4 CONC printed on the previous assay for the position.
3. Rerun the samples in this position and calculate FTI by hand (see the T-Uptake assay insert in the assay manual insert for instructions on calculating the FTI).
4. If unable to correct problem, call the Customer Support Center.

| | |
|-------------------|---|
| Code | CHECK WASTE CUP |
| Possible Cause | <ul style="list-style-type: none"> • Normal message after 25 prime cycles have been completed. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Empty waste cup. |

| | |
|-------------------|---|
| Code | CHECKSUM ERROR WAS FOUND IN THE SYSTEM NON-VOLATILE MEMORY . . . |
| Possible Cause | <ul style="list-style-type: none"> • A defective novram. • External power problems (i.e., surge, etc.). |
| Corrective Action | <ol style="list-style-type: none"> 1. Call the Customer Support Center. |

| | |
|-------------------|---|
| Code | CONCENTRATION LOW |
| Possible Cause | <ul style="list-style-type: none"> • For pipetting modes using Interactive Dilution Protocol: when the polarization value of a sample is compared to and is less than the sensitivity level. |
| Corrective Action | <ol style="list-style-type: none"> 1. See “Low test results” in the Observed Problems section. |

| | |
|----------------|--|
| Code | CRV FIT ERR ### |
| Possible Cause | <ul style="list-style-type: none"> • During calibration, data reduction for proper curve fitting was not acceptable. • Probe damaged or positioned incorrectly. • Dispenser system not working properly. • Reagent not working properly due to improper storage or handling. • Improper temperature operation. • Assay parameters incorrect. • The following page contains a table that defines the curve fit error messages. |

Corrective Action

1. Carefully inspect probe for damage or leakage. Replace probe if damaged.
2. Run Dispense Check (Test 6.3). Check for splashing in the predilution well of the sample cartridge. Observe probe positioning and correct if necessary.
3. Check all dispenser components (valve, syringes, tubing) for crimps, leaks or cracks. Replace components as needed.

NOTE: Remove syringes and check plungers for tightness in barrel. If a plunger is loose, replace the entire syringe.
4. Verify that the parameters are current (refer to the assay manual insert or to the most recent activation procedure).
5. Check dilution buffer level. If the buffer level is low or has been pooled, replace with fresh buffer and repeat calibration.
6. If reagent pack and/or calibrators are expired or have been improperly stored or handled, repeat the calibration with fresh reagent pack and/or calibrators.
7. If the assay requires sample preparation, check the accuracy of the pipettors being used.
8. Run Temperature Check (Diagnostic Test 2.1).
9. If unable to correct problem, call the Customer Support Center.

CRV FIT ERR MESSAGE DEFINITIONS

| <u>CRV FIT ERR ###</u> | <u>CURVE CHARACTERISTIC</u> |
|------------------------|-----------------------------|
| 127 | A mP too large |
| 890 | A-F span too large |
| 132 | A-B span too small |
| 084 | A-B span too large |
| 395 | B-C span too small |
| 689 | B-C span too large |
| 257 | C-D span too small |
| 416 | C-D span too large |
| 990 | D-E span too small |
| 743 | D-E span too large |
| 660 | E-F span too small |
| 310 | E-F span too large |

Call the Customer Support Center for the curve characteristics of the affected assays.

| Code | FAILED – RNG I OUT OF SPEC |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • A RNG I value is greater than or equal to 250.00 during a Pipet Check run. • Upside-down cuvette • Leaks or crimps in tubing • Air bubbles in dispense system • Buffer residue on carousel • Worn or damaged probe • Leak in sample syringe • Leak in valve block • Leak in diluent syringe |
| Corrective Action | <ol style="list-style-type: none"> 1. Check for upside-down cuvette, and repeat Pipet Check (Test 2.3). 2. Check for leaks or crimps in tubing. Secure tubing connections or replace tubing as necessary. Repeat Pipet Check. 3. Check for air bubbles in dispense system and remove. Refer to Air Bubbles in Dispenser in the Observed Problems section. Repeat Pipet Check. 4. Wash and dry probe. Inspect for damage or wear and replace if necessary. Repeat Pipet Check. 5. Wash any buffer residue on carousel, and repeat Pipet Check. 6. Replace probe, and repeat Pipet Check. 7. Perform the following procedures after replacing the probe: <ol style="list-style-type: none"> a. Boom Calibration (Test 3.2). b. 4-pot Boom Calibration (Test 3.7), if applicable. c. Unit Dose Boom Calibration (Test 3.6), if applicable. d. Probe-Positioning Check and Adjustment using the probe-positioning cartridge. 8. Replace sample syringe, and repeat Pipet Check. 9. Replace valve block, and repeat Pipet Check. 10. Replace diluent syringe, and repeat Pipet Check. 11. Recalibration of assays may be necessary after replacing probe, syringe, or valve block. Check to ensure that controls are in range. 12. If error reoccurs, call the Customer Support Center. |

| Code | HI OR LOW FOLLOWING CONCENTRATION RESULT |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Sample value above (HI) or below (LOW) the programmed therapeutic range. (Assay parameters .3 and .4 programmed by the operator). |
| Corrective Action | <ol style="list-style-type: none"> 1. Edit therapeutic range for assay if different range is desired. Refer to the assay manual insert for suggested expected results on individual assays. |
| Code | HI AFTER BLK I RESULT |
| Possible Cause | <ul style="list-style-type: none"> • Sample blank reading was greater than programmed assay parameter .20 (MX BKG). • Door open while BLK I readings were taken. • Reagent contamination. • Failure to discard previously used cuvette. |
| Corrective Action | <p>Are all samples affected?</p> <ol style="list-style-type: none"> 1. YES <p>Check the following items and perform appropriate corrective action:</p> <ol style="list-style-type: none"> a. Access door securely closed. Enable System 2.2 by editing parameter to a value of 1. b. Lamp housing cover properly seated. c. Reagent vials in correct order S-T-P except T-Uptake which is P-T-P. d. MX BKG properly programmed (parameter .20). Refer to the assay manual insert under the Assay Parameters section. e. Buffer contaminated (use a new container). f. "P" reagent contaminated (use a new reagent pack). 2. NO – Proceed. <p>Is the T4 assay being run?</p> <ol style="list-style-type: none"> 1. YES – Repeat that sample ensuring a fresh cuvette is used. If it occurs again, dilute the sample with an equal amount of Calibrator A (0.0 µg/dL) and rerun, multiplying the result by the appropriate dilution factor. 2. NO – Repeat that sample ensuring a fresh cuvette is used. Concentration of sample can be reported if the BLK I reading is less than 3 times the MN TRACER (Assay parameter .21). If the BLK I exceeds 3 times the MN TRACER, prepare a manual dilution of the sample or run a Dilution Protocol and repeat that sample. |

| Code | HI AFTER FINAL V |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • When running an REA[®] assay, sample blank reading was greater than programmed assay parameter .20 (MX BKG). • Door open while FINAL V readings were taken. • Reagent contamination. • Failure to discard previously used cuvette. |
| Corrective Action | <p>Are all samples affected?</p> <ol style="list-style-type: none"> 1. YES <p>Check the following items and perform appropriate corrective action:</p> <ol style="list-style-type: none"> a. Access door securely closed. Enable System 2.2 by editing parameter to a value of 1. b. Lamp housing cover properly seated. c. Reagent vials in correct order S-T-P. d. MX BKG properly programmed (parameter .20). Refer to the assay manual insert under the Assay Parameters section for the appropriate assay. e. Buffer contaminated (use a new container). f. "P" reagent contaminated (use a new reagent pack). 2. NO - Proceed. 3. Repeat that sample ensuring a fresh cuvette is being used. 4. If unable to correct the problem, call the Customer Support Center. |

| Code | HI INSTEAD OF CONCENTRATION |
|----------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Sample mP value falls outside the mP value for the F calibrator. • Assay run without curve in memory. • Incorrect probe positioning in predilution well. • Liquid crystal not operating properly. • Improper carousel set-up or splashing of raw sample into predilution well. • Sample follows a sample with an extremely high background. |

| | |
|-------------------|--|
| Corrective Action | <p>Does the sample(s) follow a sample with an extremely high background?</p> <p>High-background samples are indicated by one or both of the following:</p> <ul style="list-style-type: none"> - HI message prints after the BLK I result - NET I SMALL message prints instead of concentration result <ol style="list-style-type: none"> 1. YES <p>Repeat the assay, ensuring that the sample(s) does not follow a high-background sample.</p> 2. NO <p>Dilute the sample manually, or perform the Dilution Protocol procedure, if available for the assay.</p> <p>CAUTION: THE DILUTION PROTOCOL PROCEDURE IS ONLY AVAILABLE FOR SOME ASSAYS. REFER TO THE APPROPRIATE ASSAY MANUAL INSERT TO DETERMINE THE DILUTION PROCEDURES FOR SPECIFIC ASSAYS.</p> 3. Set System 2.3 to 1 for automatic return of original SPL VOL (if available for that assay), or manually edit SPL VOL to original value at completion of assay. 4. Check for proper probe positioning in the predilution well if the assay is a Mode 2 or 3 pipetting sequence. Refer to Probe-Positioning Check and Adjustment using the probe-positioning cartridge. 5. Run Photo Check. If polarization values are less than 10, do not run Photo Calibration. Call the Customer Support Center. |
|-------------------|--|

| | |
|------|--------------------|
| Code | ***HVCOEF RESET*** |
|------|--------------------|

| | |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Occurs if the HVCOEF has been automatically reset during a factory set (Test 6.2). |
| Corrective Action | <ol style="list-style-type: none"> 1. Run a Photo Calibration (Test 3.4) and Photo Check (Test 2.2). 2. Run a Pipet Check (Test 2.3). 3. Run controls against the calibration curves to verify that the curves are still acceptable. If curves are unacceptable, recalibrate. |

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| Code | ILLEGAL SAMPLE |
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| Possible Cause | <ul style="list-style-type: none"> • During REV 0 PIPETTING mode, liquid was detected in a sample cartridge that should have been empty. |
| Corrective Action | Repeat the assay run. |

| Code | INSUFFICIENT SAMPLE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Minimum sample volume not detected. • No sample in sample well. • Probe positioning incorrect in sample well. |
| Corrective Action | <ol style="list-style-type: none"> 1. Make certain that at least the minimum sample volume is present. Refer to the assay manual insert for the minimum sample volume required. 2. Wash and dry probe and run Z-boom Calibration (Test 3.5). 3. Check front to back probe positioning in the predilution well using Probe-Positioning Check and Adjustment procedure. 4. Check left to right probe positioning in sample well and adjust as necessary using Probe-Positioning Check and Adjustment procedure. 5. Replace probe and perform a Z-boom Calibration and Probe-Positioning Check and Adjustment procedure. 6. Perform a Dispense Check (Test 6.3) and observe probe positioning. If not correct, run a Boom Cal (Test 3.2) or edit the appropriate system parameter. 7. Check carousel for a broken or warped rim using Liquid-Level-Sensing Adjustment procedure or Z-boom Calibration procedure. 8. Remove the probe and flush the end of the boom arm with water. Thoroughly dry the spaces and reattach the probe. 9. If problem not resolved, call the Customer Support Center. |
| Code | INVALID DATE |

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|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Invalid date was entered during factory set. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press STOP. 2. Press SYSTEM 1.1 EDIT. Enter valid date. |

| Code | LIQ SENSE ERROR |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> Film or bubble present in reagent vials. During Dispense Check (Test 6.3) or Buffer Run, too much buffer is added to the empty vials. Splashing occurred when dispensing into the predilute or cuvette just prior to moving to the reagent well to aspirate reagent. Bubbles in the dispenser system forming a bridge between the electrodes of the probe as it moves toward the reagent well. |
| Corrective Action | <ol style="list-style-type: none"> 1. Check for bubbles and remove with an applicator stick. 2. Remove some of the buffer and repeat run (2-3 mLs should be sufficient). 3. Perform Probe Wash with distilled water as described in Section V, Maintenance. 4. Check for leaks or bubbles in the dispensing system. Replace parts as appropriate. 5. Perform the Probe-Positioning Check and Adjustment procedure using the probe-positioning cartridge. 6. If problem not resolved, call the Customer Support Center. |

| Code | LIQUID XTAL FAILURE |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> Test 3.4.4 parameter incorrect. Liquid crystal polarizer malfunctioning. |
| Corrective Action | <ol style="list-style-type: none"> 1. Check Test 3.4.4 to be sure it matches the value on the Fluorometric Standards Function Test Set Carousel. 2. Run Photo Check (Test 2.2). 3. If unable to correct problem, call the Customer Support Center. |

| Code | LIQ LEVEL HI |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• Splashing during pipetting increased the volume of liquid in the predilute well.• A drop of liquid forming a bridge between the electrodes of the probe. |
| Corrective Action | <ol style="list-style-type: none">1. Wash the probe with distilled water as described in Section V, Maintenance.2. Perform Boom Calibration (Test 3.2).3. Check probe positioning by performing Probe-Positioning Check and Adjustment procedure as described in Section V, Maintenance.4. If unable to correct problem, change the probe and electrodes.5. If still unable to correct problem, call the Customer Support Center. |

| Code | LIQ LEVEL LO |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• The reagent level is insufficient in one of the unit dose cartridges.• The Z-boom calibration is incorrect. Usually occurs on several cartridges on same run or on a regular basis.• System 8.9 may be set incorrectly; should be 300.• System 8.10 may be set incorrectly; should be 137. |
| Corrective Action | <ol style="list-style-type: none">1. Replace the cartridge causing the error.2. Perform a Z-boom Calibration (Test 3.5).3. Edit System 8.9 to 300 and System 8.10 to 137 if necessary.4. Call the Customer Support Center. |

| Code | LLS FAIL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Liquid-level sense failure during the second pipetting revolution. • Liquid on probe is creating a liquid bridge between two electrodes. • Probe tip damaged or mispositioned. • Splashing in the predilution well. • Buffer salt bridge has formed between two electrodes. • Used cuvettes not removed from carousel. • Inlet tube not seated all the way into buffer. • Undetected empty buffer bottle. • Probe thumbscrew not properly secured. • Thumbscrew washer missing. • Liquid-level-sensing electrodes not properly inserted into end of boom arm. |
| Corrective Action | <ol style="list-style-type: none"> 1. Wash and dry probe. Verify the presence of a nylon washer between the thumbscrew and the metal bar on the boom arm. 2. Check cuvettes to be sure they were empty when the run was initiated. 3. Push tube all the way into buffer bottle. 4. Replace buffer if empty or adjust platform for correct detection. 5. Press PRIME three times, checking for air bubbles. Refer to procedure for air bubble removal. 6. Remove and reseal the probe; be sure the thumbscrew is secure but not overtight. 7. Remove the probe and wash the front end of the boom arm with water. Thoroughly dry the spaces in the boom and reattach the probe. Verify the presence of a nylon washer between the thumbscrew and the metal bar on the boom arm. 8. Check probe position. Observe a Dispense Check (Test 6.3). Adjust as needed. 9. If problem is not resolved, call the Customer Support Center. |

| Code | LOW INSTEAD OF CONCENTRATION |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • mP reading value higher than the mP used in the calibration curve for the A calibrator. • Assay run without calibration curve in memory. • Assay run with wrong type reagent pack. • Air bubble trapped in sample. • Incorrect probe positioning in predilution well. • Calibration carousel label not read correctly or wrong carousel used to calibrate the assay. |
| Corrective Action | <p>Are all samples affected?</p> <ol style="list-style-type: none"> 1. YES – Check to be sure calibration curve is in memory and correct reagent pack is being used before performing the assay. Check to make sure the carousel label was read properly and that a Calibration carousel was used to calibrate the assay. Observe Dispense Check (Test 6.3) for proper probe positioning. 2. NO – Repour sample, assuring no air bubbles are trapped, then repeat assay. If low result for a sample is repeated, report out as less than sensitivity of the assay, referring to the assay manual insert for that assay. |
| Code | > MX BKG |
| Possible Cause | <ul style="list-style-type: none"> • When performing an abused drug assay, this message appears instead of the concentration if BLK I is greater than assay parameter XX.20 (MX BKG), regardless of the System 6.7 (T PRINT) setting. The BLK I value will print followed by a HI flag. • During an abused drug assay run, parameter XX.3 (BKG FAC) is set to 0. |
| Corrective Action | <div data-bbox="568 1512 1421 1627" style="border: 1px solid black; padding: 5px;"> <p>WARNING: THE PATIENT SAMPLE MUST NOT BE DILUTED AND RERUN. ASSAY PARAMETER XX.20 (MX BKG) SHOULD NOT BE EDITED TO A GREATER VALUE THAN IS FOUND FOR THAT ASSAY IN THE ASSAY PARAMETERS SECTION OF THE ASSAY MANUAL INSERT.</p> </div> <ol style="list-style-type: none"> 1. Check assay parameter XX.3 (BKG FAC) for the abused drug assay being run. If parameter XX.3 is set to 0, call the Customer Support Center for the proper value. |

| Code | NET I LARGE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • During calibration, net intensity was greater than or equal to 25.5 times greater than assay parameter .21 (MN TR). • Dispenser system not working properly. • Reagent not working properly due to improper storage or handling. • Expired or contaminated Pipet Check Solution. • Assay not activated after installing new memory board. • Faulty source lamp. • Factory set not properly performed. • Assay not properly activated. |
| Corrective Action | <ol style="list-style-type: none"> 1. Press PRIME and observe dispenser for possible leaks or slipping sample syringe. Ensure that buffer is being dispensed through probe. Correct problem as applicable. 2. Examine probe carefully for damage. Ensure that the sample probe is 1 mm longer than the liquid-level sensors. Replace if necessary. Check front to rear probe positioning. 3. Check for bubbles in each reagent vial. Remove bubbles and rerun. 4. Use a new reagent pack. 5. If problem occurs with more than one assay, use new container of buffer. 6. Verify the reagent pack label was read correctly on the calibration printout. 7. Check the MN TR (X.21) to ensure it is greater than fifty. If it is less than fifty, use System 5.1 to activate assay parameters. Contact the Customer Support Center for necessary codes. 8. Check the accuracy of the optics by performing Photo Check (Test 2.2). Perform Photo Cal (Test 3.4) if necessary. 9. Run Pipet Check (Test 2.3) with fresh solution (LN 9531-02). 10. Check proper positioning of source lamp in housing. Replace lamp, if necessary. 11. Contact the Customer Support Center. |

| Code | NET 1 TOO SMALL |
|----------------|--|
| Possible Cause | <ul style="list-style-type: none"> • During calibration, net intensity was less than assay parameter .21 (MN TR). • Cuvette upside down in carousel. • Dispenser system not working properly. • Reagent not working properly due to improper storage or handling. • Expired or contaminated Pipet Check Solution. • Assay not activated after installing new memory board. • Faulty source lamp. • Assay not properly activated. <ol style="list-style-type: none"> 1. Set up new carousel with all cuvettes properly oriented. 2. Press PRIME and observe dispenser for possible leaks or slipping sample syringe. Ensure that buffer is being dispensed through probe. Correct problem as applicable. 3. Examine probe carefully for damage. Ensure that the sample probe is 1 mm longer than the liquid-level sensors. Replace if necessary. Check front to rear probe positioning. 4. Check for bubbles in each reagent vial. Remove bubbles and rerun. 5. Use a new reagent pack. 6. If problem occurs with more than one assay, use new container of buffer. 7. Verify the reagent pack label was read correctly on the calibration printout. 8. Check the MN TR (XX.21) to ensure it is greater than fifty. If it is less than fifty, use System 5.1 to activate assay parameters. Contact the Customer Support Center for necessary codes. 9. Check the accuracy of the optics by performing Photo Check (Test 2.2). Perform Photo Cal (Test 3.4) if necessary. 10. Run Pipet Check (Test 2.3) with fresh solution (LN 9531-02). 11. Check proper positioning of source lamp in housing. Replace lamp, if necessary. 12. Contact the Customer Support Center. |

| Code | NET I SMALL |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • During an assay run, net intensity was less than assay parameter .21 (MN TR). • Cuvette upside down. • Dispenser system not working properly. • Reagent not working properly due to improper storage or handling. • Sample had an extremely high background. • An REA[®] chemistry has detected an extremely high concentration of analyte in a sample. • Assay was not activated after installing new memory board. |
| Corrective Action | <ol style="list-style-type: none"> 1. Ensure that all cuvettes are right side up. 2. Repeat assay. <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>WARNING: SAMPLES IMMEDIATELY ADJACENT TO AN UPSIDE-DOWN CUVETTE OR FOLLOWING A SAMPLE WITH AN EXTREMELY HIGH BACKGROUND MAY GIVE ERRONEOUS RESULTS BECAUSE OF SPLASHING OR POTENTIAL CARRYOVER. REPEAT THESE SAMPLES.</p> </div> <ol style="list-style-type: none"> 3. Check that sample syringe retainer is secure. Observe dispenser for possible leaks. Ensure that buffer is being dispensed through probe. 4. Examine probe carefully for damage. Ensure that the delivery probe is 1mm longer than the liquid-level-sensing probes. 5. Check for bubbles in "T" vial. Remove bubbles and rerun. 6. Use fresh reagent pack (do not dilute or pool reagents). 7. Rerun sample using Dilution Protocol or manually dilute sample 1:1 and repeat. 8. If running an REA chemistry, check the cuvette for a more intense coloration compared to other samples. If the color is more intense, reassay the sample using the Dilution Protocol. 9. If problem affects more than one assay, use a new container of X SYSTEMS[™] Dilution Buffer. 10. Verify the reagent pack label was read correctly on the assay printout. 11. Check the MN TR (X.21) to ensure it is greater than fifty. If it is less than fifty, use System 5.1 to activate assay parameters. Contact the Customer Support Center for activation codes. 12. Run a Photo Check (Test 2.2). Perform Photo Cal (Test 3.4) if necessary. 13. Run Pipet Check (Test 2.3) with fresh solution (LN 9531-02). 14. Replace source lamp after ensuring lamp is properly seated in lamp housing. 15. Call the Customer Support Center. |

| Code | NO AIR SPACE |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Appears when probe does not detect an air space between the foil and the reagent fluid level of a unit dose cartridge. • Bubbles in the reagent wells or reagent wells overfilled. • TEFLON[®] worn on the fluid-sensing electrodes. • Probe not able to complete puncture of foil within allotted time according to System 8.9 UD WAIT. • Probe misaligned - electrodes too close to reagent well edge. • Probe weight loose. |
| Corrective Action | <ol style="list-style-type: none"> 1. Realign probe by performing a Unit Dose Boom Calibration (Test 3.6). 2. Check tightness of mounting screws of boom arm weight and tighten if necessary. 3. Check the probe positioning and foil puncture in the reagent wells. Correct if necessary. 4. If isolated to one cartridge, replace cartridge. 5. Check the condition of the TEFLON on the electrodes. If worn, replace electrodes. 6. Perform a Z-boom Calibration (Test 3.5). 7. Contact the Customer Support Center. |
| Code | NO AVG AVAILABLE |
| Possible Cause | <ul style="list-style-type: none"> • During calibration or assay run with SPL replicates of 2 or more, one or more samples resulted in NET I SMALL so no average was possible. • Occurs when running an abused drug assay, with System 6.7 (T PRINT) set at 1, SPL REPS set at 2 or more, and one or more samples resulted in HI or LOW. |
| Corrective Action | <ol style="list-style-type: none"> 1. Refer to printed error message NET I SMALL. 2. If running an abused drug assay, set System 6.7 to 0 and reprint the data by pressing SYSTM 4.1 RUN. One or more positions in the group showing NO AVG AVAILABLE should print HI or LOW. |

| Code | NO FOIL FOUND |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • The probe is poorly positioned and the electrodes miss the reagent well completely. • The fluid-sensing electrodes are malfunctioning. |
| Corrective Action | <ol style="list-style-type: none"> 1. Check the unit dose cartridge causing the error to ensure that the foil is intact. If it is, perform a Z-boom Calibration (Test 3.5). 2. Check the position of the probe and correct as necessary, using Probe-Positioning Check and Adjustment procedure for TEFLON® coated stainless steel probe in the Maintenance section of this manual. Check System 8 parameters against the System 8 parameter printout received with the instrument. 3. Replace the fluid-sensing electrodes per instructions given in the Maintenance section of this manual. |

| Code | NO SAMPLES PIPETTED |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • During calibration or assay, no liquid was detected in any of the sample cartridges. • Too little sample in sample cartridges. • Probe not detecting fluid properly. • Probe positioned incorrectly in sample well or predilution well. • Liquid-level-sensing electrodes not properly inserted into end of boom arm. |
| Corrective Action | <ol style="list-style-type: none"> 1. Set up new carousel being sure the correct volume is used. 2. Place carousel into instrument. 3. If problem continues, wash and dry probe. 4. Perform Boom Calibration (Test 3.2). 5. Check liquid-level sensing of electrodes using Test 4.4. 6. Check probe attachment to end of boom arm. Ensure that thumbscrew is secure. 7. Remove the probe and flush the front end of the boom arm with water. Thoroughly dry the spaces and reattach the probe. 8. Replace probe. 9. Perform the Probe-Positioning Check and Adjustment procedure. 10. If unable to correct problem, call the Customer Support Center. |

| Code | NO VALID ANSWER |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> When using the Interactive Dilution Protocol, the units are edited to an inappropriate unit, this message will print instead of a concentration. When using the Interactive Dilution Protocol, the concentration of a sample falls between dilution ranges, or none of the net polarizations for a sample are within the calibration curve; this message will print instead of a concentration. When using the Interactive Dilution Protocol, an error such as an upside down cuvette, NET I SMALL, PREDIL LEVEL LOW, INSUFFIC SAMPLE, PIPETTE ERROR, or SPL CRTRDGE MISS prints instead of a NET P value, and NO VALID ANSWER prints instead of a concentration. |
| Corrective Action | <ol style="list-style-type: none"> Ensure that the units parameter XX.13 is set at the appropriate value indicated in the assay manual insert before attempting Interactive Dilution Protocol. Manually dilute the sample with X SYSTEMS™ Dilution Buffer or drug-free normal human serum and rerun using the Interactive Dilution Protocol. |
| Code | NONE DETECTED |
| Possible Cause | <ul style="list-style-type: none"> Running an abused drug assay with System 6.7 (T PRINT) set at 1, and the concentration is less than the threshold value specified in assay parameter .4 (THRSHLD). |
| Corrective Action | <ol style="list-style-type: none"> No corrective action is required as this is not an error code but a message signifying that the result is less than the stored threshold. This message will appear instead of the result and no NET P or BLK I values will print. |
| Code | NOT CALIBRATED |
| Possible Cause | <ul style="list-style-type: none"> Printed in the assay header when a unit dose assay is run without calibrating the assay. The assay will still run but no concentration values will be printed. |
| Corrective Action | <ol style="list-style-type: none"> Calibrate the assay in the unit dose mode. Rerun the samples. If unable to correct problem, call the Customer Support Center. |

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| Code | NOVRAM X BAT LOW |
| Possible Cause | <ul style="list-style-type: none">• During power-up checks, this message will appear if the battery is low. Power-up will continue. |
| Corrective Action | <ol style="list-style-type: none">1. Call the Customer Support Center. |
| Code | ***PBIAS RESET*** |
| Possible Cause | <ul style="list-style-type: none">• Occurs if the PBIAS has been automatically reset during a factory set (Test 6.2). |
| Corrective Action | <ol style="list-style-type: none">1. Run a Photo Check (Test 2.2).2. Run controls against the calibration curves to verify that the curves are still acceptable. If curves are unacceptable, recalibrate. |
| Code | PHO CHECK GAIN MUST MATCH CAL GAIN |
| Possible Cause | <ul style="list-style-type: none">• During Photo Check or Photo Cal, Test 2.2.1 did not match Test 3.4.1. |
| Corrective Action | <ol style="list-style-type: none">1. Edit Test 2.2 and Test 3.4 parameters to match values on Fluorometric Standards Function Test Set Carousel. |
| Code | PIPETTE ERROR |
| Possible Cause | <ul style="list-style-type: none">• Sampling or pipetting error.• Syringes not functioning. |
| Corrective Action | <ol style="list-style-type: none">1. Make sure that correct volume of sample is in the sample well.2. Observe the dispensing process with a buffer run. If probe position is not correct, run a Boom Cal (Test 3.2) or edit the appropriate system parameter.3. Observe syringe movement during a buffer run. Look for any obstructions or improper movement.4. Contact the Customer Support Center. |

| Code | P0 TOO SMALL |
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| Possible Cause | <ul style="list-style-type: none"> • During calibration, polarization measured for calibrator A was less than assay parameter .16 (MN POLA). • Wrong calibrator in first sample wells. • Reagents have been stored incorrectly. • Probe positioning incorrect in predilution well. <p>NOTE: For T-Uptake, polarization measured for calibrator F was less than assay parameter .16 (MN POLA).</p> |
| Corrective Action | <ol style="list-style-type: none"> 1. Set up new carousel ensuring that calibrators are put in correct order with the proper number of replicates. 2. Perform the Probe-Positioning Check and Adjustment procedure using the probe-positioning cartridge to define the correct System 3.4 parameter, if necessary. 3. Ensure that the assay is properly activated. 4. Use new reagent pack. 5. Use new buffer. 6. If problem occurs with more than one assay, use new container of buffer. 7. If unable to correct problem, call the Customer Support Center. |

| Code | PREDIL LEVEL HI |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Predilution well overfilled. • Reuse of sample cartridges. |
| Corrective Action | <ol style="list-style-type: none"> 1. Check predilution well for overfilling. 2. Verify that used sample cartridges are discarded. 3. Run a Z-boom Calibration (Test 3.5). 4. If problem not resolved, call the Customer Support Center. |

| Code | PREDIL LEVEL LO |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Sample not being sensed in predilution well. |
| Corrective Action | <ol style="list-style-type: none"> 1. Run a Dispense Check (Test 6.3) to verify that the appropriate amount of diluent is present in the predilution well. 2. Press PRIME and observe for leaks or crimps in the tubing. 3. Ensure the syringes are clamped properly. 4. Ensure buffer is being dispensed from the probe. If buffer is not being dispensed, check the tubing connection. Replace the valve block. 5. Check the probe attachment on the end of the boom arm. Ensure the thumbscrew is secure. 6. Remove the probe and flush the front end of the boom arm with distilled water. Thoroughly dry the spaces and reattach the probe. 7. Check the probe positioning using the Probe-Positioning Check and Adjustment procedure. 8. Perform a Boom Calibration (Test 3.2). 9. If unable to resolve the problem, replace the probe. 10. Call the Customer Support Center. |
| Code | RANGE TOO LARGE |
| Possible Cause | <ul style="list-style-type: none"> • During calibration, difference in polarization or percent fluorescence intensity between replicates of calibrators was greater than assay parameter .15 (MX DEV). • Air bubble in sample in sample well. • Splashing of sample into predilution well while loading cartridges. • Calibrators not put into sample cartridges in correct number of replicates. • Calibrators not put in correct order with reps sequential on the carousel. • Probe dirty, damaged, or positioned incorrectly. • Reagent not responding properly. • Dispenser System not functioning properly. • Inlet tube not seated all the way into buffer. • Door opened with System 2.2 disabled during run. • Assay parameter .15 (MX DEV) not set correctly. |

Corrective Action

1. Check assay parameter .15 for correct value (See the assay manual insert for assay being run). If incorrect, edit to the proper value.
2. Wash and dry probe. Check for damage.
3. Inspect the carousel carefully to ensure all the locking tabs are in place. If a locking tab is missing, the cuvette will not be held securely. Discard the carousel and order a replacement.
4. Verify that calibrator replicates are loaded properly.
5. Prepare the carousel with new calibrators.
6. Observe probe positioning and dispensing by performing a Dispense Check (Test 6.3). Adjust as necessary. Check dispensing system for leaks, crimps, bubbles or loose syringe clamps. Replace as necessary.
7. Perform a Probe Carryover Check (Section IV). Replace the probe if carryover is more than 1.5%.
8. Reseat the inlet tube into buffer. If unable to correct the problem, use a new container of buffer.
9. Reenable door lock (System 2.2 set to 1) and repeat run.
10. Perform Photo Check (Test 2.2) and take appropriate action.
11. Perform Pipet Check (Test 2.3) and take appropriate action.
12. Replace probe, perform Probe-Positioning Check and Adjustment procedure using probe-positioning cartridge or Z-boom Calibration (Test 3.5).
13. If performing an assay that requires pretreatment of a sample, check the accuracy of the pipettors.
14. Replace syringes, and valve block.
15. Use a new reagent pack.
16. If unable to correct problem, call the Customer Support Center.

Code

REAGENT LEVEL LO

Possible Cause

- Reagent reaches unacceptable level during run.

Corrective Action

1. Ensure that probe is properly positioned by performing Boom Calibration (Test 3.2).
2. Replace reagent pack and repeat run.
3. If problem not resolved, call the Customer Support Center.

| Code | SAMPLE LEVEL HI |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• Z-boom home incorrectly positioned.• Sample well filled too high.• Bubbles present in sample well. |
| Corrective Action | <ol style="list-style-type: none">1. Perform a Z-boom Calibration (Test 3.5).2. Ensure an appropriate volume of sample is present in the sample well.3. Ensure no bubbles are present in the sample well. If present, remove with an applicator stick.4. If the problem is not resolved, call the Customer Support Center. |

| Code | SAMPLE LEVEL LO |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• Sample volume reaches an unacceptable level during run. |
| Corrective Action | <ol style="list-style-type: none">1. Ensure that an appropriate amount of sample is present in the sample well.2. Check the probe attachment on the end of the boom arm. Ensure the thumbscrew is secure.3. Perform a Z-boom Calibration (Test 3.5).4. If the problem is not resolved, call the Customer Support Center. |

| Code | SPAN LESS THAN MIN SPAN |
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| Possible Cause | <ul style="list-style-type: none">• Assay not activated.• During calibration, difference in either polarization or percent fluorescence between A and F calibrators was less than assay parameter XX.17, MN SPAN.• A and/or F calibrators not in correct position.• Improperly sampled F calibrator.• Tube not seated all the way into buffer.• Probe damaged or positioning incorrect.• Reagent not working due to improper storage or handling.• Wrong calibrators used for reagent system. |

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| Corrective Action | <ol style="list-style-type: none"> 1. Ensure that the assay is properly activated and that assay parameter XX.17 was edited appropriately. 2. Set up new carousel with calibrators in correct order. 3. Ensure assay parameter XX.5 (CAL VOL) is set to the correct value for the reagent system being used. Refer to the assay manual insert. 4. Ensure assay parameter XX.6 (CAL REPS) is set to 2, if running a batch calibration. 5. Use correct reagent pack for calibrator set. 6. Reseat tube in buffer carton. 7. Observe a Dispense Check (Test 6.3) for proper probe positioning in predilution well. 8. Press PRIME and observe dispenser for possible leaks or slipping sample syringe. Correct problem as applicable. 9. Use new container of buffer. 10. Perform Photo Check and take appropriate action. 11. If unable to correct problem, call the Customer Support Center. |
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| Code | SPL CRTRDGE MISS |
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| Possible Cause | <ul style="list-style-type: none"> • Sample cartridge missing during a run using Interactive Dilution Protocol. |
| Corrective Action | <ol style="list-style-type: none"> 1. Inspect carousel for any positions missing a sample cartridge. Rerun the affected samples. 2. If unable to resolve the problem, call the Customer Support Center. |

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| Code | SPLS NOT MONOTONIC |
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| Possible Cause | <ul style="list-style-type: none"> • During calibration, polarization or percent fluorescence intensity values were not in descending order. (For T-Uptake or other assays where specified, in ascending order.) • Calibrators not in correct alphabetical order. • Sample volume incorrect on one or more calibrators. • Calibrator concentrations incorrect. • Assay parameter XX.14 (CRV FIT) programmed incorrectly. |
| Corrective Action | <ol style="list-style-type: none"> 1. Set up new carousel being sure calibrators are in correct order and replicated properly. 2. Wash and dry probe. Inspect for damage. 3. Press PRIME and observe dispenser for possible leaks or slipping sample syringe. Correct problem as applicable. |

4. Run another assay and check for proper operation. If second assay works properly, rerun first assay using new set of calibrators.
5. Replace probe if more than one assay exhibits problem.
6. Verify the CRV FIT (XX.14) parameter is programmed correctly. Refer to the appropriate assay section of the assay manual insert.
7. If unable to correct problem, call the Customer Support Center.

| Code | SPLVOL ILLEGAL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none"> • Occurs during a unit dose run when sample volume and calibrator volume are not the same. • Occurs when trying to perform Dilution Protocol on unit dose assays or on an assay where Dilution Protocol is not programmed. • Occurs during a Specific Proteins assay run if assay parameters XX.5 (CAL VOL) and XX.7–XX.12 (CONC A–CONC F) are set to 0. |
| Corrective Action | <ol style="list-style-type: none"> 1. Check assay parameters XX.1 (SPL VOL) and XX.5 (CAL VOL) making sure they are the same number. If they are not the same, edit the appropriate parameter. Refer to the appropriate assay section of the assay manual insert. 2. Do not attempt Dilution Protocol for unit dose. NOTE: The assay run will be completed, only those sample volumes that are illegal will be flagged. The flagged positions will not be assayed. 3. Check the Specific Proteins Calibrators package insert for the correct value of parameters XX.5 (CAL VOL) and XX.7–XX.12 (CONC A–CONC F). Edit the value(s) to agree with the package insert. 4. Call the Customer Support Center. |

| Code | TEMP CAL FAIL |
|-------------------|---|
| Possible Cause | <ul style="list-style-type: none">• When running Temp Cal (Test 3.1):<ul style="list-style-type: none">a. Incorrect temperature entered.b. A large THM OFF value change was necessary.c. Carousel moved during calibration.d. Ambient temperature affecting the degrees C entered. |
| Corrective Action | <ol style="list-style-type: none">1. Press STOP.2. Repeat Temp Cal a couple of times with fresh cuvettes.3. If unable to resolve the problem, call the Customer Support Center. |

| | |
|-------------------|---|
| Code | > = THRESHOLD |
| Possible Cause | <ul style="list-style-type: none"> When running an abused drug assay with System 6.7 (T PRINT) set at 1, and the concentration is greater than or equal to the Threshold value specified in assay parameter .4 (THRSHLD). |
| Corrective Action | <ol style="list-style-type: none"> No corrective action is required as this is not an error code but a message signifying that the result is greater than or equal to the stored Threshold. This message will appear instead of the concentration and no NET P and BLK I values will print. |
| Code | > = T |
| Possible Cause | <ul style="list-style-type: none"> When running an abused drug assay with System 6.7 (T PRINT) set at 0, and the concentration is greater than or equal to the Threshold value specified in assay parameter .4 (THRSHLD). |
| Corrective Action | <ol style="list-style-type: none"> No corrective action is required as this is not an error code, but a message signifying that the result is greater than or equal to the stored Threshold. This message will appear after the concentration and the NET P and BLK I values will print. |
| Code | ***** PRINTED INSTEAD OF BLK I |
| Possible Cause | <ul style="list-style-type: none"> Extremely high Blank I reading. |
| Corrective Action | <ol style="list-style-type: none"> If isolated to one or a few samples, check to see whether patient(s) have been injected with a fluorescing compound for another diagnostic procedure. Run Photo Check (Test 2.2). Do any values fall out of specifications? NO – Proceed to Step 3. YES – Refer to “Photo Check Out of Specifications”. Run a different assay. Do BLK I values still print out all *****? NO – Use new reagent pack for original assay. YES – <ol style="list-style-type: none"> Use a new container of buffer. Call the Customer Support Center with all information if problem continues. |

| Code | ***** PRINTED INSTEAD OF 1 RESULT ON PIPET CHECK |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none">1. Use a fresh bottle of Pipet Check Solution and repeat Pipet Check, ensuring that the cuvettes are clean and the Pipet Check Solution is carefully dispensed into the sample well of the sample cartridge.2. Run Photo Check. Do any values fall out of specifications? NO – Proceed. YES – Refer to “Photo Check Out of Specifications”.3. Wash and dry the probe.4. Perform a buffer run to observe the dispensing process. Check the probe’s positioning in the sample well if necessary.5. Check the dispenser, probe and interconnect tubing for possible leaks. Replace tubing and probe if necessary.6. Run an assay. Are the correct values printed? YES – Use a fresh vial of Pipet Check solution and repeat Pipet Check. NO – Call the Customer Support Center with all information.7. If unable to resolve problem, call the Customer Support Center. |

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| PROBLEM | Air bubbles in dispenser |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none"> 1. Tap tubing during prime cycle to dislodge air bubbles. 2. Insert inlet tube all the way into buffer. 3. Straighten crimped tubing. Replace tubing if unable to straighten. Check all connections to be sure they are secure. 4. Tighten tubing connection at the valve block. 5. If air bubble is trapped on sample syringe plunger tip, run several prime cycles to dislodge the bubble. If this is not successful, remove the syringe from the valve housing (as described in the Maintenance section of this manual), disassemble and clean the plunger with distilled water and a lint-free tissue. Reassemble the syringe and return it to the valve housing. Prime several times. 6. If air bubbles are trapped on the diluent syringe plunger tip, do the following: <ol style="list-style-type: none"> a. Unscrew the buffer inlet tubing and remove the buffer bottle. b. Move the boom arm to the center of the instrument by pulling on the boom-arm barcode reader assembly. Place a test tube or other receptacle under the probe. <p>CAUTION: PLACING A TEST TUBE UNDER THE PROBE IS NECESSARY TO PREVENT BUFFER SPILLS INSIDE THE INSTRUMENT.</p> c. Unscrew the syringe retainer. d. Push the plunger up and pull down rapidly to dislodge bubbles. e. Remove and discard the test tube with buffer. f. Reattach the syringe retainer to the drive block ensuring that the plunger is reseated properly. g. Place the buffer container back in the instrument and reattach the inlet tubing. h. Prime the system three times to dislodge bubbles. It may be necessary to repeat step (d) to completely dislodge bubbles. i. If bubbles remain, remove and disassemble syringe. j. Wipe plunger tip with a non-abrasive tissue or other suitable material. Wipe the inside of the glass barrel with a cotton swab. k. Fill syringe with buffer or deionized water and tap gently to remove air bubbles. l. Reattach diluent syringe. m. Prime system three times. 7. Reseat valve block. 8. If bubbles continue to appear, replace inlet tubing, diluent syringe, sample syringe or valve block. |

| PROBLEM | Boom arm strikes reagent vials |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> 1. Check reagent pack to be sure it is properly positioned and vial caps have been removed. Reseat reagent pack if necessary. 2. Push reagent vials down into reagent pack to be sure they are fully seated. 3. Pack may tip when reagents get low if pack hinge does not move freely. To prevent this, place a wedge under the lid support pin. 4. Disable door lock sensor (System 2.2 = 0) and observe where the probe strikes the vial. <p>If the probe strikes the edge of the vial as the boom moves vertically, the R-Boom position step numbers may not be correct. Perform Boom Calibration (Test 3.2).</p> <p>If the probe strikes the vial as the boom moves horizontally, check the length of the probe tubing to ensure it is sufficient and is not hindering the movement of the boom arm.</p> <p>Perform a Z-boom Calibration (Test 3.5) to ensure the proper height of the boom arm. Check that the probe is inserted all the way up into the boom arm.</p> 5. Enable door lock sensor (System 2.2 = 1). 6. If unable to correct problem, call the Customer Support Center with all information. <p>CAUTION: CHECK PROBE TIP FOR POSSIBLE DAMAGE AFTER OBSERVING THIS PROBLEM. IF DAMAGE IS OBSERVED REPLACE PROBE.</p> |

| PROBLEM | Boom Calibration (Test 3.2) will not work properly | | | | | | | | | | | | | | | | | | |
|-------------------|--|-------|--------|----|-------|-------|----|-------|---------|----|-------|---------|----|-------|---------|-----|-------|---------|------|
| Corrective Action | <div>1. Print Test 3.2. Check the parameters printed with the values given below. If the values stored in the memory of the instrument are not within ± 2 steps, edit them accordingly.</div> <div>These parameters determine where the barcode reader will begin to look for the reagent pack label.</div> <table><tr><td>3.2.1</td><td>RPK ST</td><td>72</td></tr><tr><td>3.2.2</td><td>RPK P</td><td>46</td></tr><tr><td>3.2.3</td><td>PRD CUP</td><td>49</td></tr><tr><td>3.2.4</td><td>PRD SRM</td><td>16</td></tr></table> <div>These parameters determine where the barcode reader will begin to look for the carousel label.</div> <table><tr><td>3.2.5</td><td>CAR STR</td><td>217</td></tr><tr><td>3.2.6</td><td>CAR STC</td><td>1697</td></tr></table> | 3.2.1 | RPK ST | 72 | 3.2.2 | RPK P | 46 | 3.2.3 | PRD CUP | 49 | 3.2.4 | PRD SRM | 16 | 3.2.5 | CAR STR | 217 | 3.2.6 | CAR STC | 1697 |
| 3.2.1 | RPK ST | 72 | | | | | | | | | | | | | | | | | |
| 3.2.2 | RPK P | 46 | | | | | | | | | | | | | | | | | |
| 3.2.3 | PRD CUP | 49 | | | | | | | | | | | | | | | | | |
| 3.2.4 | PRD SRM | 16 | | | | | | | | | | | | | | | | | |
| 3.2.5 | CAR STR | 217 | | | | | | | | | | | | | | | | | |
| 3.2.6 | CAR STC | 1697 | | | | | | | | | | | | | | | | | |

2. When the values have been edited and stored, repeat the Boom Calibration.

NOTE: When Boom Cal is repeated, the probe positions will not be correct. Every time this test is run, the instrument uses default values stored in memory to position the probe. These values are not the probe positions previously stored in Boom Cal.

3. If the problem occurs with the carousel label, ensure the calibration (CAL) carousel is being used. If necessary, relabel the carousel.
4. Ensure that the new System 3 parameters that have been defined are stored with the **STORE** key before exiting Test 3.2. To check the parameters after they are stored, perform a buffer run.
5. If unable to resolve the problem, call the Customer Support Center.

PROBLEM

Calibration Curves not stable for 14 days - QC out of range

Corrective Action

1. Are all levels of TD_x controls outside the ranges stated in the assay manual insert for the specific reagent system in question?
 - YES – Proceed to step #2.
 - NO – Use a new vial of the control whose value is outside the accepted range. If the value for the new vial of control is within range, there is no problem with the calibration curve stored in memory. If the value is still outside the range, proceed to step #2.
2. Are all reagent systems exhibiting the problem?
 - YES – a. To determine whether the instrument is functioning properly, run a Photo Check (Test 2.2), a Pipet Check (Test 2.3) and a Temperature Check (Test 2.1). Analyze the results of each check and take the appropriate corrective action if any results are not within specifications. If all results are within specifications, proceed to (b).
 - b. If the buffer container has been changed, all assays may need to be recalibrated.
 - c. Check the probe's positioning in the predilution well to ensure proper mixing.
 - d. Replace the dispenser components; probe, sample syringe, diluent syringe and valve. Ensure the inlet tubing and interconnect tubing are not crimped. If a crimp is found, reposition or replace the tube.
 - e. If the problem recurs frequently, call the Customer Support Center.
 - NO – Proceed to step #3.

3. Does the calibration curve instability occur only with an assay requiring a sample preparation step?

YES – a. Check the accuracy and reproducibility of the pipettors used to dispense the appropriate sample preparation reagent and the samples.

b. Ensure the sample preparation reagent is dispensed into the centrifuge tubes before the sample is added (except for the Total T₃ PLUS assay).

c. Ensure the sample preparation reagent and sample are thoroughly mixed before centrifugation.

d. Ensure the sample preparation reagent has not expired.

e. If centrifugation is necessary, check the centrifuge RPM. Calibrate the centrifuge if necessary.

f. Recalibrate using a new package of calibrators and controls.

g. Remove reagent pack from instrument promptly after assay completion. Recap vials and store properly.

NO – Proceed to step #4.

4. Open a new reagent pack and run all levels of controls. Are the controls within range when the new reagent pack is used?

YES – The reagent pack which exhibited the problem was subjected to some trauma. The following items could cause this problem:

- a. Leaving the opened reagent pack in the instrument will cause evaporation.
- b. Putting the reagent vial caps on the wrong vials will contaminate the reagents.
- c. Spilling any solution into the vials will cause contamination of the reagents.
- d. Improper storage of reagent pack.

NO – If any of the changes listed below have been made since the last calibration, the change could be the cause of the calibration curve change. Recalibrate the reagent system, note the date of calibration in the maintenance log and monitor the stability of the new calibration curve.

- new lot number of reagent
- new lot number of buffer
- replacement of a dispenser component
- performance of any instrument calibration procedure (Diagnostic Test 3).

| PROBLEM | Calibration fails to meet specifications | | | | |
|--|---|-----------|--------------------|---------------------|-----------|
| Corrective Action <ul style="list-style-type: none"> • PERR or ERR too large • RMSE too large | <ol style="list-style-type: none"> 1. RMSE and PERR or ERR specifications are to be used only as guidelines. If controls are in range, proceed with reporting patient results. 2. If controls are outside the specified range, was the run terminated during the processing of the curve by pressing STOP or opening the door and a reprint of the data obtained? NO – Proceed. YES – Repeat the run. 3. If all controls are outside the specified range, wash and dry the probe. Set up new calibration carousel assuring there are no air bubbles in the samples or in the dispenser tubing. Assure that reagents, calibrators and controls are mixed prior to use. 4. Does problem occur with more than one assay? NO – <ol style="list-style-type: none"> a. Check calibrator concentrations to be sure they are programmed correctly. b. Replace reagent pack, calibrators and buffer. Repeat calibration after replacing each item to isolate cause of problem. c. If unable to correct problem, call the Customer Support Center. YES – Proceed. 5. Observe a Dispense Check (Test 6.3) to verify probe performance. 6. Run Photo Check (Test 2.2). Does it pass specifications? NO – Refer to “Photo Check out of specifications”. YES – Proceed. 7. Run Pipet Check (Test 2.3). Does it pass specifications? NO – <ol style="list-style-type: none"> a. Replace dispenser components in the order indicated. Repeat Pipet Check after replacing each item. <table> <tr> <td>1 – probe</td> <td>2 – sample syringe</td> </tr> <tr> <td>3 – diluent syringe</td> <td>4 – valve</td> </tr> </table> b. If unable to correct problem, call the Customer Support Center. YES – Proceed. 8. Run Temperature Check (Test 2.1). Does it meet specifications? NO – Refer to Temp Check out of specification. YES – Proceed. 9. Replace buffer container. 10. Use new reagent pack and calibrators. 11. If unable to correct problem, call the Customer Support Center. | 1 – probe | 2 – sample syringe | 3 – diluent syringe | 4 – valve |
| 1 – probe | 2 – sample syringe | | | | |
| 3 – diluent syringe | 4 – valve | | | | |

| PROBLEM | Controls fail to print during successful calibration run (no errors printed) |
|-------------------|--|
| Possible Cause | <ul style="list-style-type: none"> • Minimum sample volume was not detected. • Sample was not present in sample well. |
| Corrective Action | <ol style="list-style-type: none"> 1. Repeat the control run ensuring that sufficient sample volume is present. Refer to the assay manual insert for the minimum sample volume required for the assay. 2. If unable to correct the problem, call the Customer Support Center. |
| PROBLEM | Display blank |
| Corrective Action | <ol style="list-style-type: none"> 1. Turn the power switch, located in the rear of the instrument, off. 2. Reseat the power cord on the TD_x analyzer and in the outlet. 3. Turn the rear panel power switch on. 4. Does unit display [DATE __ __ . __ __ . __ __] ? <ul style="list-style-type: none"> NO – <ol style="list-style-type: none"> a. Check outlet to be sure it has proper power. b. Check that rear panel was installed properly with interlock switch covered. c. If unable to resolve problem, make a note whether printer responds (by advancing platen) when power switch is turned on and call the Customer Support Center with the information. If a letter or symbol appears in right-hand side of display, refer to next PROBLEM. d. Check power supply lights to the left of the display under the buffer door. If any lights are out, note which one(s). Turn instrument off and call the Customer Support Center with the information. YES – Proceed. 5. Enter and store the correct date and time. When the display shows [READY], unit is ready for operation. Calibration curves previously run will still be stored in memory. |

| PROBLEM | Display shows single character |
|--|---|
| <u>CHARACTER DISPLAYED</u> | <u>POSSIBLE CAUSE</u> |
| 1, 2, 3, 4, 5, 6, 7, 8 or 9 < or > on power up : or ; < or > during editing | <p data-bbox="570 436 862 472">Memory failure (slot #2)</p> <p data-bbox="570 531 1354 567">Attempting to enter an unacceptably small (<) or large (>) number.</p> <p data-bbox="570 583 1435 674">If < or > shows in the display while a parameter is being edited, the value which has been entered is not acceptable. Press STOP and reenter the correct acceptable volume.</p> <p data-bbox="570 699 1333 789">If any character shows in the display either during the power up sequence, while the instrument is at [READY] or during normal operation of the instrument, refer to the instructions below.</p> <ol data-bbox="570 810 1435 1381" style="list-style-type: none"> <li data-bbox="570 810 1393 869">1. If any of the characters listed above show in the right-hand side of the display turn the instrument off and wait 30 seconds. <li data-bbox="570 884 1040 919">2. Turn power on and initialize system. <li data-bbox="570 934 1252 970">3. If problem reoccurs, turn instrument off and unplug it. <li data-bbox="570 984 841 1020">4. Remove rear panel. <li data-bbox="570 1035 1435 1209">5. Remove appropriate printed circuit boards (PCBs) one at a time. Clean PCB contacts with methanol on a wipe and reseal board. Ensure the components are facing toward the right and the board is aligned on the upper and lower guide rails. Ensure each PCB “clicks” into position when reseated. A significant amount of force is required to do this. <li data-bbox="570 1224 841 1260">6. Replace rear panel. <li data-bbox="570 1274 1263 1310">7. Plug instrument in and turn power on. Initialize system. <li data-bbox="570 1325 1349 1381">8. If problem reoccurs, call the Customer Support Center with all information. |

| PROBLEM | NOVRAM errors | |
|---|---|--|
| Corrective Action | The possible cause for this failure depends on the operation being performed when the error condition occurred. Refer to the list below to determine the possible cause and corrective action which should be taken. Note that some conditions only display a message while others will both display and print a message. If unable to correct problem, call the Customer Support Center. | |
| CONDITION | CORRECTIVE ACTION | POSSIBLE CAUSE |
| BOOM CALIBRATION being run. | <ol style="list-style-type: none"> 1. Press STOP. 2. Repeat Boom Calibration (Test 3.2). | <ul style="list-style-type: none"> • Unable to store parameter in memory. |
| Calibration run (Displays and prints NOVRAM ERROR - CRV FIT). | <ol style="list-style-type: none"> 1. Press STOP. 2. Repeat calibration with fresh calibrator samples. | <ul style="list-style-type: none"> • Calibration curve data not stored correctly. |
| Power up sequence (initialization). | <ol style="list-style-type: none"> 1. Turn power off and wait 30 seconds. 2. Turn power on and initialize system. 3. If problem reoccurs, turn power off and unplug instrument. 4. Remove rear panel. 5. Remove PCB #2, clean board contacts with methanol on a non-abrasive tissue, and reseat board into card cage. 6. Replace rear panel. 7. Plug instrument in and turn power on. Initialize system. | <ul style="list-style-type: none"> • Memory failure. (Board #2) |

| CONDITION | CORRECTIVE ACTION | POSSIBLE CAUSE |
|---|--|--|
| PHOTO CALIBRATION being run (Displays and prints error message). | <ol style="list-style-type: none"> 1. Press STOP. 2. Print parameters for Test 3.4 and verify gain, intensity and polarization values are the same as those values on the Fluorometric Standards Function Test Set Carousel label. 3. Edit any parameters which do not match so the instrument parameters are the same as the Fluorometric Standards Function Test Set Carousel label. 4. Rerun Photo Calibration (Test 3.4). | <ul style="list-style-type: none"> • Unable to store parameter in memory. |
| Self-diagnostic check after first test of the day (displays and prints NOVRAM ERROR-DAILY CHECK). | <ol style="list-style-type: none"> 1. Call the Customer Support Center. | <ul style="list-style-type: none"> • Self-diagnostic check run failed. |
| TEMPERATURE CALIBRATION being run. | <ol style="list-style-type: none"> 1. Press STOP. 2. Repeat Temperature Calibration (Test 3.1). Assure correct temperature value is entered. | <ul style="list-style-type: none"> • Unable to store parameter in memory. |
| PIPET CHECK. | <ol style="list-style-type: none"> 1. Call the Customer Support Center. | <ul style="list-style-type: none"> • Unable to set MN TR (assay parameter .21) in assays. |

| PROBLEM | Erratic test results |
|-------------------|---|
| Corrective Action | <p>Review the following items and take corrective action as appropriate.</p> <ol style="list-style-type: none"> 1. Cuvette upside down. 2. Disposable component was not clean, or foreign matter was present. 3. No calibration curve in memory. (Check date on header, if no calibration curve has been stored, calibration date will be 00/00/00.) 4. Air bubbles in sample well. 5. Sample splashed into predilution chamber. 6. Air bubbles in tubing or syringes. 7. Syringes slipping or leaking. Syringe clamp loose or misaligned. 8. Probe dirty or damaged. Wash and dry probe or replace. 9. Tubing loose on liquid heater connector. 10. Carousel dirty. 11. Probe bent or squeezed causing improper mixing or possible carryover. 12. Probe not properly positioned over predilution chamber causing improper mixing. Run a Dispense Check (Test 6.3) and observe probe performance in the predilution well. Change the probe if necessary. 13. Probe not properly positioned over predilution or sample wells, causing improper sampling. Refer to Probe-Positioning Check and Adjustment procedure using probe-positioning cartridge. 14. Valve leaking; reseal or replace valve block. 15. Locking tabs broken on carousel. This prevents the cuvettes from being held stationary during the test. Discard carousel and purchase a new one. 16. Photomultiplier tube (PMT) fatigue due to access door being left open. Run a Photo Check (Test 2.2). 17. The door was opened, with System 2.2 disabled, during the run. 18. To determine whether the instrument is functioning properly, run a Photo Check (Test 2.2), a Pipet Check (Test 2.3) and a Temperature Check (Test 2.1). Analyze the results of each check and take the appropriate corrective action if any results are not within specification. 19. If unable to correct problem, call the Customer Support Center with all information. |

| PROBLEM | Frequent display of AIR, OPT or LIQ temperature |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none"> 1. If "AIR or LIQ or OPT T" = 0.0, call the Customer Support Center. 2. Check cooling fan inlet, located in the center of the underside of the TD_x analyzer, for partial obstruction. Remove any obstruction found. Refer to the air-fan filter cleaning procedure in the Maintenance section. 3. Ensure that there is at least a 6" clearance on all sides of the system. 4. Access door left open. Keep door closed at all times when not inserting reagents or carousel. 5. Be sure room temperature is within the specifications. 6. Be sure instrument is not in direct sunlight or draft from fan or air duct. 7. Run Temperature Check (Test 2.1) and check results against specifications. 8. If LIQ temperature is too high, prime two or three times. 9. If problem persists, call the Customer Support Center with all information. |
| PROBLEM | High test results |
| Corrective Action | <ol style="list-style-type: none"> 1. Are most samples affected? <p>NO – a. Repeat sample (use Dilution Protocol if "HT" printed instead of concentration.)</p> <p>CAUTION: THE DILUTION PROTOCOL PROCEDURE IS ONLY AVAILABLE FOR SOME ASSAYS. REFER TO THE APPROPRIATE ASSAY MANUAL INSERT TO DETERMINE THE DILUTION PROCEDURES FOR SPECIFIC ASSAYS.</p> <p>b. If value does not correlate with original result, proceed to step 2.</p> <p>YES – Proceed.</p> |

2. Review the following items and take corrective action as appropriate.
 - a. Serum accidentally dispensed or splashed into cuvette or predilution chamber in sample cartridges.
 - b. Assay parameters not correct. Verify that assay parameters match values listed in the assay manual insert or kit enclosure.
 - c. Assay parameters not correct. Verify that assay parameters match values listed in the assay manual insert or kit enclosure.
 - d. Carryover on probe. Wash and dry probe. Replace probe if problem still exists.
 - e. Air bubbles in tubing or syringes. Remove or replace tubing as needed.
 - f. Slipping or leaking diluent syringe. Reseat or replace as needed.
 - g. Inlet tube not fully seated into buffer container.
 - h. Leaking valve. Reseat or replace valve block and repeat run.
 - i. Perform the Probe-Positioning Check and Adjustment procedure.
 - j. Controls out of range. Recalibrate assay and rerun.
3. If unable to correct problem, call the Customer Support Center with all information.

| PROBLEM | Initialization sequence showing in display |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none"> 1. Enter and store date and time. 2. When displays [READY] unit is ready for operation. 3. If problem recurs, check for possible source of power failure within laboratory. 4. Turn power off, reseal power cord, turn power on. 5. If unable to correct problem, call the Customer Support Center. |

| PROBLEM | Low test results |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> 1. Check for bubbles in sample in sample well. 2. Verify that assay parameters match values listed in the assay manual insert or kit enclosure. 3. Probe height not properly adjusted. Refer to Z-boom Calibration (Test 3.5). 4. If using the Barcode Override procedure, ensure the reagent pack being used corresponds to the assay number used in the barcode override. 5. Press PRIME and observe dispenser for possible leaks, air bubbles or slipping syringes. Correct problem as applicable. 6. Assure proper probe positioning in sample well and predilution well by observing a Dispense Check (Test 6.3). If necessary, perform a Probe-Positioning Check and Adjustment procedure using probe-positioning cartridge. 7. If problem still occurs, change the probe. 8. If controls are out of range, recalibrate assay. 9. Reagent vials out of order in reagent pack. Repeat assay using a new reagent pack. 10. Repeat assay using a new buffer container. 11. If unable to correct problem, call the Customer Support Center. |

| PROBLEM | No results printed |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> 1. Was date, time and assay name printed? NO – <ol style="list-style-type: none"> a. Attempt to redisplay and reprint data using System 4.1 and 4.2, respectively. b. Turn TD_x System power off. NOTE: All results are deleted when the system is powered off. c. Ensure printer ribbon is threaded properly. d. Move printhead to the center of the guide shaft. e. Turn the TD_x System power on. Verify that the printer returned to its left-hand home position. Repeat run after initializing TD_x analyzer. f. If problem reoccurs, clean and lubricate the printer. YES – Proceed. 2. Is power supply light #5 lit? NO – Call the Customer Support Center. (Use System 4.2 to display results.) YES – Proceed. 3. If unable to correct problem, call the Customer Support Center. |

| PROBLEM | Noise coming from analyzer |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> Did noise occur during operation? <ul style="list-style-type: none"> NO – <ol style="list-style-type: none"> Check cooling fan intake under the center of the instrument for obstruction. Remove obstruction. Clean the air-fan filter if necessary. Attempt to run an assay. If results are within control ranges, proceed with assays and notify the Customer Support Center. If unable to operate instrument, call the Customer Support Center. YES – Proceed. Press STOP. Open access door and check following items. Take corrective action as appropriate. <ol style="list-style-type: none"> Reagent vial caps not removed. Reagent pack not seated properly. Reagent vial not fully pushed down in reagent pack. Carousel not properly seated. Vial cap liner stuck on top of vial. Observe boom arm movement (remember to disable door lock by editing System 2.2 to 0 to make it possible to watch operation). Ensure that the probe tubing length is sufficient so it does not hinder the boom arm movement. Ensure liquid-level-sensing probes are properly attached in the end of the boom arm. Ensure the thumbscrew is tight. Enable door lock (System 2.2 = 1). Remove buffer door and check syringes for breakage. Press PRIME and observe syringe operation. Take corrective action as necessary. If beeper is stuck, turn TD_x analyzer power off. Wait a few seconds, then turn TD_x analyzer power on and initialize system. If necessary, edit System 2.1 to 0 to turn the beeper off. If beeper is periodically activated, ensure that access door is kept closed when at [READY]. Ensure the reagent pack and carousel have been removed at the completion of the run. If unable to correct problem, call the Customer Support Center. |

| PROBLEM | Paper jams or fails to advance |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> 1. Re-thread paper onto printer platen being sure it feeds straight. 2. Adjust black paper guides on bar behind platen so paper is guided properly. Guides should be just touching the paper edges. 3. If paper is sticking to printer cover, remove cover and spray cover with an antistatic spray. 4. Check paper roll to be sure it is not binding inside printer. Using slight pressure, spread open the metal plates which hold the spindle, to avoid binding the paper. 5. Replace paper roll, ensuring that the paper feeds from the underside of the roll. 6. Check to be sure correct paper is used. If paper is too smooth, it will slip on the platen instead of advancing. Order paper from Abbott (LN 9520-20). 7. Clean the platen with isopropanol. 8. Clean and lubricate printer. 9. Use a blade screwdriver to gently bend the brass foot on the printhead a little away from the paper. |
| PROBLEM | Photo Check out of specifications |
| Corrective Action | <ol style="list-style-type: none"> 1. a. When TD_x analyzer display shows [READY] press TEST 2.2.1 DISPLY. If the gain value showing in the display is not the same as the gain on the Fluorometric Standards Function Test Set Carousel label, edit the displayed value to agree with the label. b. Check the gain, intensity and polarization in Test 3.4 If they do not match the label on the Fluorometric Standards Function Test Set Carousel, edit the Test 3.4 values to agree with the label. c. Ensure that the same Fluorometric Standards Function Test Set Carousel is used for the Photo Check procedure that was used for the Photo Calibration procedure. Fluorometric Standards Function Test Set Carousel(s) may be labeled with the applicable TD_x analyzer serial number(s) by placing a label on the inner ring opposite the factory-installed carousel label. d. Repeat Photo Check (Test 2.2). 2. Has Fluorometric Standards Function Test Set Carousel been left outside of the storage box? <ol style="list-style-type: none"> NO – Proceed. YES – a. Place in storage box for one hour. b. Rerun Photo Check. c. If still out of specifications, proceed. 3. Clean all ampules with lens paper, then rerun Photo Check. |

4. Clean aperture located on the left wall of the lamp housing.
5. Check optics lenses to see if they have slipped out of place.
6. Ensure no air bubbles are trapped in lower portion of ampules. Invert carousel several times to dislodge bubbles if necessary.
7. If the polarization range is greater than 2.5 mP, run a CV Check. Are results within acceptable limits?
 - NO – Proceed to step #8.
 - YES – a. Rerun Photo Check.
 - b. If results are still out of specifications, call the Customer Support Center. Proceed with test runs being sure to verify all control results.
8. Replace the lamp.
9. Perform Photo Cal. Recalibration of all assays may be necessary after running Photo Cal before running patient samples. Verify control results before running patients. Recalibrate assays where controls are not within acceptable range.
10. If unable to correct problem, call the Customer Support Center.

| PROBLEM | Pipet Check out of specifications |
|---|---|
| <p>Corrective Action</p> <ul style="list-style-type: none"> • If error message printed refer to printed error codes “AVG I TOO SMALL” and “AVG I TOO LARGE” for Pipet Check. | <ol style="list-style-type: none"> 1. Check for upside-down cuvette, and repeat Pipet Check (Test 2.3). 2. Check for leaks or crimps in tubing. Secure tubing connections or replace tubing as necessary. Repeat Pipet Check. 3. Check for air bubbles in sample wells. Repeat Pipet Check. 4. Wash and dry probe. Inspect for damage or wear and replace if necessary. Repeat Pipet Check. 5. Wash any buffer residue on carousel, and repeat Pipet Check. 6. Replace probe, and repeat Pipet Check. 7. Perform the following procedures after replacing probe: <ol style="list-style-type: none"> a. Boom Calibration (Test 3.2). b. 4-pot Boom Calibration (Test 3.7) if applicable. c. Unit Dose Boom Calibration (Test 3.6) if applicable. d. Probe-Positioning Check and Adjustment using the probe-positioning cartridge. 8. Replace sample syringe, and repeat Pipet Check. 9. Replace diluent syringe, and repeat Pipet Check. 10. Replace valve block, and repeat Pipet Check. 11. Recalibration of assays may be necessary after replacing probe, syringe, or valve block. Check to ensure that controls are in range. 12. If error reoccurs, call the Customer Support Center. |

| PROBLEM | Power Supply lights do not light |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none"> 1. Attempt normal operation by running an assay. Does unit operate normally? NO – a. Note which light(s) are not lit (#1 is at the top). b. Call the Customer Support Center with this information. YES – Proceed. 2. Indicator light is burned out. This will not affect instrument operation. Proceed with assays and notify the Customer Support Center that light bulb is burned out. |
| PROBLEM | Prime does not operate |
| Corrective Action | <ol style="list-style-type: none"> 1. Does display show [READY]? NO – a. If an error message is displayed refer to appropriate displayed message in this section. b. If [DATE ____ . ____ . ____] in display enter and store date and time. When [READY], proceed to step 2. YES – Proceed. 2. Press STOP and PRIME. Do diluent and sample syringe drive blocks move down? NO – a. Press PRIME again to assure it was actuated. Verify that System 2.1 is set to 1. Listen for “beep” to assure button was actuated. b. Turn power off then on and re-initialize the instrument by entering and storing the correct date and time. c. If instrument still fails to prime, call the Customer Support Center. YES – If buffer is being dispensed out probe, perform assay. If no buffer is dispensed, proceed to step #3. 3. Was valve housing just installed? NO – a. Be sure inlet tube is seated all the way down into buffer container. b. Check container to be sure there is sufficient buffer (buffer platform may be mispositioned). c. Reseat or replace inlet tube from valve to buffer. d. Reseat or replace valve housing. e. Reseat or replace interconnect tubing. f. If unable to correct problem, call the Customer Support Center. YES – Remove valve housing and reseat. Follow Valve Block Replacement procedure. (It may be necessary to rotate the valve 180° and reinstall the valve two or three times if the valve core needs realignment). |

| PROBLEM | Printer does not print |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none"> 1. Remove printer cover. Grasp printhead and move it back and forth on guideshaft. Does it move smoothly? NO – Clean and lubricate printer. YES – Proceed. 2. Replace ribbon and check printer operation by using Test 5.4.1. 3. Power TD_x System off and on. Verify that the printer line feeds and the platen turn. 4. Is #5 Power Supply light on? NO – Call the Customer Support Center with information. |
| PROBLEM | Printhead jams |
| Corrective Action | <ol style="list-style-type: none"> 1. Clean and lubricate printer. 2. Reposition ribbon on guides being sure the ribbon is on top of movable brass guide attached to the printhead. 3. If one ribbon spool is near the end, make sure it is rewinding properly. If not rewinding properly, move gray ribbon reverse bar to opposite position on printhead. If problem reoccurs, call the Customer Support Center. 4. Adjust black paper guides on bar behind platen so paper is guided properly. The guides should be just touching the edges of the paper. 5. Use a blade screwdriver to gently bend the brass foot on the print-head a little away from the paper. 6. If unable to correct problem, call the Customer Support Center. |
| PROBLEM | Printout squeezed together |
| Corrective Action | <ol style="list-style-type: none"> 1. Clean and lubricate printer. 2. Reposition ribbon on guides ensuring the ribbon is on top of movable brass guide attached to the printhead. 3. If unable to correct problem, call the Customer Support Center. |

| PROBLEM | Rapid syringe wear |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> 1. Remove the syringe(s) from the valve block according to the Syringe Replacement procedure in Section V, Maintenance. 2. Reattach carefully to avoid cross threading. It may be necessary to turn the syringe 180 degrees when reattaching it so the syringe seats easily into the detent on top of the drive block. 3. Reattach the syringe clamp or retainer, ensuring that the plunger is seated securely in the detent on the drive block. 4. If problem continues, replace valve block. 5. If problem continues, call the Customer Support Center. |
| PROBLEM | Sample skipped |
| Corrective Action | <ol style="list-style-type: none"> 1. Ensure the correct volume of sample has been placed into the sample well. 2. Ensure the probe connector on the boom arm is clean and properly secured. Both overtightening and undertightening of the thumbscrew securing the probe can cause fluid-sensing failures. 3. Wash and dry the probe. 4. Run Boom Calibration (Test 3.2). Ensure the probe is in the center (from left to right and front to back) of the sample well by observing a Dispense Check (Test 6.3). Check the front-to-back probe alignment using the probe-positioning cartridge. 5. Check liquid-level sensing of probe using the Liquid-Level-Sensing Adjustment procedure. 6. Remove the probe and flush the end of the boom arm with distilled water. Thoroughly dry the spaces in the boom arm and reattach the probe. 7. If unable to correct problem, replace the probe. 8. If unable to correct problem, call the Customer Support Center. |
| PROBLEM | Splashing or foaming in the predilution well during dispensing |
| Corrective Action | <ol style="list-style-type: none"> 1. Follow the probe inspection procedure for the probe to determine the condition of the probe. If it is damaged, replace it. 2. If the probe is not damaged, check the probe positioning over the predilution well by performing the Probe-Positioning Check and Adjustment procedure. 3. If unable to correct problem, call the Customer Support Center. |

| PROBLEM | Temperature Check out of specification |
|-------------------|---|
| Corrective Action | <ol style="list-style-type: none"> 1. Check cuvettes to be sure they are all right side up. 2. Repeat Temperature Check (Test 2.1). 3. If Temperature Check is still out of specification, call the Customer Support Center. |

| PROBLEM | Test (assay) does not start after RUN |
|-------------------|--|
| Corrective Action | <ol style="list-style-type: none"> 1. Does display show [READY]? <ul style="list-style-type: none"> NO – Proceed. YES – Press RUN carefully, being sure you can feel the button move slightly. With System 2.1 memory set to 1, listen for “beep” to assure button was actuated. If problem still exists, proceed. 2. Can you hear the carousel revolving? <ul style="list-style-type: none"> NO – <ol style="list-style-type: none"> a. Press STOP then press RUN carefully being sure you can feel the button move slightly. b. If assay still does not start, turn power off then on again and initialize system. Run assay again. c. If problem continues, call the Customer Support Center. YES – Proceed. |

3. Does the assay name appear in the display?

NO – a. Wait five (5) minutes.

b. If message appears in display refer to appropriate page in Troubleshooting Section.

c. If assay does not proceed normally, press **STOP** and call the Customer Support Center.

YES – a. Normal operation. Wait for assay to be completed.

b. If assay does not proceed normally, press **STOP** and call the Customer Support Center.**PROBLEM****Z-boom Calibration not working properly****Corrective Action**

Review the four problems listed below (A, B, C or D); find the one which most nearly describes the problem you are experiencing. Take the corrective action as listed.

A. More than a 1 step spread in step # in the five positions.

This may be caused by one of two items, either the volume of buffer in the sample wells is not exactly 50 μ L, or the sample cartridge ring on the carousel has been broken or is warped. To isolate the cause of the problem, proceed as follows:

1. Switch the sample cartridges that are reading incorrectly to a position that is reading correctly.
2. Reread the step number where fluid is being detected by pressing **NEXT**.
3. If the incorrect reading stays with the sample cartridge moved to the new carousel position, the amount of buffer in the sample well is not correct. Accurately pipette 50 μ L of X SYSTEMS™ Dilution Buffer into five clean sample cartridges and repeat the Z-boom Calibration.
4. If the incorrect reading stays with the carousel position, the sample cartridge ring on the carousel is broken or warped. Order a new carousel. Use another carousel to repeat the Z-boom Calibration. The defective carousel may be used for assays by adding extra sample to the sample well until the replacement is received.

B. Sample Missing

1. The solution in the sample well must be buffer or some other solution that will be conductive. Distilled or deionized water will not be detected.
2. Wash and carefully dry the probe and repeat the test. Verify probe attachment on the boom arm is correct. Ensure the thumbscrew is tight.

-
3. Watch where the probe is positioned as it goes into the sample well. Ensure the probe is centered in the well. If it is not positioned properly, edit System 3.3 as needed to center the probe (Refer to Probe-Positioning Check and Adjustment procedure for sample well using the probe-positioning cartridge or perform a Boom Calibration (Test 3.2).
 4. Ensure the 50 μ L of buffer is pipetted accurately.
 5. Check the liquid-level sensing of the probe using Test 4.4.
 6. If unable to resolve the problem, call the Customer Support Center.
- C. Check the accuracy of the fluid volume used when Z-boom Cal was performed.

If a large volume of sample, greater than 100 μ L, was dispensed, the Z-boom HM selected by the TD_x analyzer may be an invalid number (greater than 252). System 3.14 will then need to be edited to the last correct Z-boom HM step number. Repipette the samples and repeat Z-boom Cal (Test 3.5).

- D. When Test 3.5 is repeated, the step number is not 172 or 173.

This is normal operation. Every time this test is run the instrument uses a default value stored in the memory and allows the operator to calibrate the Z-boom to the correct position with the 0 and • keys. Once the **STORE** key is pressed, the calibrated Z-boom home step # is stored as System 3.14 until the calibration procedure is performed again or System 3.14 is edited. If you want to verify the Z-boom home is set correctly, perform the Liquid-Level-Sensing Adjustment procedure, steps 1 through 18, or a Dispense Check (Test 6.3).

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LOT NUMBER INTERPRETATION

For Use with Activation Codes and Other Lot Number Referrals

In the Abbott Laboratories TD_x Lot Numbering System, the first two-digit numeric code indicates the month and the year of assignment. These codes are assigned sequentially beginning with 01 and proceeding through 96 before repeating 01. The second three-digit numeric code identifies each lot. For example, for month 50 the number is assigned starting with 50001X100 through 50999X100. Upon reaching 50999X100 in the same month, the sequence will revert to 50001X200 through 50999X200 and repeat the cycle with X300, X400, etc. Therefore, the number 50001X200 is greater than 50999X100.

NOTE: The suffix designation X = Q, M, or SV.

In some cases, it is possible for a single base lot of material to be processed in stages requiring the last two digits of the lot numbers to change from 00 to 01, 02, etc. For example, the lot number sequence may be 50001X100 followed by 50001X101 in which case the 50001X101 is the higher lot number.



Assay Activation Record

[illegible]
